Chapter 5. Public Health

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Chapter 5 analyzes the potential exposure of people to pathogenic microorganisms and other contaminants that may be present in both Class A EQ and Class B biosolids at levels that may cause disease. Pathogens (or pathogenic organisms) are disease-causing organisms, including certain bacteria, parasites, and viruses. Other contaminants—or "pollutants"—discussed in this analysis are (1) substances that are regulated under the GO in provisions that limit ceiling concentrations and cumulative loadings in biosolids and (2) other substances regulated under the California Health and Safety Code that may be found in biosolids in concentrations at which they could adversely affect human health; these include trace metals and synthetic organic compounds (SOCs). For purposes of the analysis, exposure to pathogens or pollutants is assumed to occur through:

- direct contact (direct ingestion or adsorption),
- inhalation, or
- ingestion of food
  - produced directly from soils amended with biosolids or
  - produced indirectly from such soils (i.e., consumption of animals or wildlife that consumed vegetation or crops growing in the soils).

The information in this chapter is based on:

- the quantitative risk assessments completed by the EPA to support the development of the Part 503 regulations limiting the beneficial reuse of sewage sludge (biosolids) (ABT Associates 1993),
- extensive review of the literature published since the completion of the Part 503 risk assessments to determine whether assumptions used in the risk assessments are still valid and whether new information is available that might change the evaluation of potential risks from use of biosolids, and
- review of state regulations pertaining to biosolids and consultations with qualified experts.

Controversy exists over the risk assessments performed by the EPA and whether the EPA's assumptions regarding appropriate level of risk are protective of public health (Harrison et al. 1999); questions regarding this issue are being addressed by the EPA and others. The National Research Council in 1996 assembled a panel of experts to assess the issue. The panel concluded that continued research on pathogen-monitoring techniques was needed, that restrictions on animals grazing on biosolids-amended fields should be reevaluated, and that the testing of sludges for the presence of toxics should continue so that the risk assessment assumptions can be refined as needed as better data become available (National Academy of Sciences 1996). It is not the purpose of this EIR analysis to resolve such controversies. This analysis addresses the effects of implementing a project: adoption of a GO that would allow for beneficial use of biosolids in California that is protective of public health, the environment, and water quality.

The EPA commissioned the National Academy of Sciences' National Research Council (NRC) to reassess the scientific basis of the Part 503 regulations and address public health concerns. Although this study recommended the resultant 2002 study Biosolids Applied to Land: Advancing Standards and Practices reviewed the regulations that govern the land application of biosolids from the following perspectives: (1) review the risk-assessment methods and data used to establish concentration limits for chemical pollutants in biosolids to determine whether they are the most appropriate approaches (including assessing how well EPA had responded to the recommendations of the 1996 assessment); (2) review the current standards for pathogen elimination and their adequacy for protecting public health; and (3) explore whether approaches for conducting pathogen risk assessment can be integrated with those for chemical risk assessment. Biosolids Applied to Land did not address the issues of dioxins or radioactivity in sewage sludge, both of which were the subject of separate analyses.

Biosolids Applied to Land concluded that while there is "no documented scientific evidence that the Part 503 rule has failed to protect public health … further research is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids" (National Research Council 2002). The NRC offered almost 60 specific recommendations for addressing public concerns, scientific uncertainties, and data gaps in the science of biosolids application. The study's overarching recommendations for the EPA were to: (1) use improved risk-assessment methods to better establish standards for chemicals and pathogens; (2) conduct a new national survey of chemicals and pathogens in sewage sludge; (3) establish a framework for an approach to implement human health investigations; and (4) increase resources to EPA's biosolids program.

The EPA responded to these recommendations in a preliminary strategy published in the Federal Register of April 9, 2003. In its response, the EPA has pledged to: (1) update the scientific basis of Part 503 by conducting research in priority areas; (2) strengthen the biosolids program by evaluating the results of completed, ongoing, and planned studies both inside and outside of EPA; and (3) continue ongoing activities to enhance communications with outside associations and the public over the Part 503 rules, to the extent that it is able to do so given budgetary constraints. (EPA. 2003)

The potential for biosolids to adversely affect groundwater underlying application sites or surface water adjacent to such sites is discussed in Chapter 3, “Soils, Hydrology, and Water Quality”. Potential impacts associated with inhalation of biosolids during application or tilling of soils where biosolids have been applied are analyzed in this chapter; however, the effects on air quality are discussed in Chapter 10, “Air Quality”. Effects on soils and crops are discussed in Chapter 4, “Land Productivity”.

This assessment focuses on the public health protection provided by the Part 503 regulations and the public health provisions of the proposed GO in light of the conditions that exist in California. It also considers whether there is new scientific evidence that warrants a reconsideration of the protections provided by these existing and proposed regulations. Finally, the assessment evaluates the need to modify any provisions or add other mitigation to protect public health.

On December 31, 2003, the EPA announced in the Federal Register its final action plan in response to the NRC recommendations arising from the Biosolids Applied to Land report. At the same time, it announced the results of its required review of existing biosolids regulations to identify additional toxic pollutants that may need to be regulated.

The final action plan identifies the following near-term projects to be initiated in the next two or three years (the final action plan uses the term "sewage sludge" to mean biosolids):

- biennial review under Clean Water Act Section 405(d)(2)(C);
- compliance assistance and enforcement actions;
- methods development, optimization, and validation for microbial pollutants in sewage sludge to improve the methods and procedures for determining the effectiveness of established pathogen reduction/elimination treatment processes;
- field studies of application of treated sewage sludge to determine whether the pathogen and chemical requirements of Part 503 are being met;
- targeted survey of selected chemical pollutants;

- participation in a workshop to be held by the Water Environment Research Foundation (WERF) to involve stakeholders in evaluating the next steps to develop an incident tracking process;
- exposure measurement workshop to compliment the WERF workshop;
- assess the quality and utility of data, tools, and methodologies to conduct microbial risk assessments on pathogens;
- support for the Pathogen Equivalency Committee;
- development and application of analytical methods for detecting pharmaceutical and personal care products in sewage sludge;
- publish the proceedings of the EPA-USDA workshop on emerging infectious disease agents and issues associated with animal manures, biosolids, and other similar by-products;
- support the February 2004 "Sustainable Land Application Conference;"
- review criteria for molybdenum in land-applied treated sewage sludge; and
- improve stakeholder involvement and risk communication.

The EPA has decided not to do two projects identified in its preliminary strategy (68 FR 17379) -- a re-evaluation of the risk assessment used for pollutants regulated or evaluated in Round One and a molecular pathogen tracking exposure study -- because of the ongoing studies identified in the final action plan, changing priorities, and limited resources.

Pursuant to the biennial review required under Clean Water Act Section 405(d)(2)(C), the EPA conducted screening analyses to determine whether there are additional toxic pollutants in biosolids that need to be regulated. Beginning with a list of 803 candidate pollutants (including pollutants already regulated), the EPA undertook a screening process to eliminate those that were either: already regulated; previously evaluated and not found to be a hazard; were not reported to be present in US sewage sludge in the literature; had no human health benchmark; or, is not the subject of another on-going assessment (those pollutants will be prioritized for possible inclusion in a targeted survey).

The EPA applied a hazard-based screening to the 40 pollutants identified after the initial screening. This looked at the potential exposure risks for three scenarios. As a result, the EPA identified 15 chemicals, which have hazard quotients that either exceed one for human receptors of equal or exceed one for ecological receptors. The EPA will undertake a more refined risk assessment and risk characterization process for these chemicals. No specific new regulations are proposed at this time. A future rulemaking may be undertaken by the EPA, pending the completion of the risk assessment and characterization process and consideration of the results.

In addition, in a related action, the EPA submitted a written request to the Centers for Disease Control and Prevention on December 23, 2003 to review the available information on reported human health effects from the land application of biosolids. (U.S. Environmental Protection Agency. 2003x) The Biosolids Applied to Land report concluded that while there is no documented scientific evidence that the Part 503 rule has failed to protect public health, persistent uncertainty exists about the potential health impacts of land application of biosolids, and additional research and investigation are warranted. The EPA's request responds to the NRC report's recommendation that a protocol be established for systematic reporting, tracking, investigative follow-up, and data retention.

Environmental Setting

Introduction

This “Environmental Setting” section describes the pathogenic microorganisms that may be present in biosolids that could affect exposed hosts, inducing illness. The setting describes key disease-causing organisms and provides general information on their concentrations in biosolids; describes infectious doses (the numbers or concentrations of organisms that could induce illness in humans); and summarizes available information ~~in scientific~~ in scientific literature about their survival in soils, surface waters, and groundwater.

Summary data for the past few years are provided on the incidence of disease caused by known pathogens as reported by county and city health departments throughout California.

In addition, published reports on new disease outbreaks and newly discovered pathogens were reviewed. Emerging pathogens are organisms responsible for new, re-emerging, or drug-resistant infections whose incidence in humans has increased within the past two decades or whose incidence threatens to increase in the near future. Included are such pathogens as *E. coli* O157:h7 and *Cyclospora*, which have caused several outbreaks in California. Because of a lack of cost-effective monitoring methods, pathogens in the environment are difficult to measure, but research laboratories are developing new techniques for detection (De Leon et al. 1990, De Leon and Gerba 1990, De Leon et al. 1992, Straub et al. 1995, Droffner and Brinton 1995, Patel et al. 1998) Also, information on survivability and infectious dose is not yet available for these pathogens. Despite the paucity of information on emerging pathogens, however, some discussion of the diseases they cause and their potential presence is warranted, in part because it is important to note that new pathogens not normally present in California can be transferred (for example, by travelers or by importation of contaminated food or animals) at any time and can be introduced into the sewage system, and from there into biosolids. Where there are potential pathogens that pose risks that may be greater than those presently being reported, this information is noted.

Appendix E provides supporting information divided into three parts. ~~Refer to Appendix E (~~Part 1~~) for more~~ has detailed information on the individual pathogens and disease incidence in California. ~~Appendix E (~~Part 2~~)~~ contains a description of the EPA Part 503 risk assessment process, ~~which describes~~including the types of analyses undertaken to evaluate the risks of exposure to non-pathogenic contaminants and to establish the levels to protect public health that form the basis for the limitations established in the GO. Part 3 contains information on endocrine disruptors. The National Research Council's Biosolids Applied to Land: Advancing Standards and Practices examined the scientific basis for Rule 503, particularly from the point of view of the selection of chemicals and pathogens that are subject to Rule 503 and the effectiveness of the controls embodied in the rule.

Pathogens

Pathogens of Concern

Sewage and sewage sludges may contain a wide variety of pathogens shed by humans (who may or may not exhibit outward signs of any disease). This analysis addresses those pathogen groups that have been identified in scientific literature as being of regulatory concern or to which waterborne or foodborne disease outbreaks in our society (not necessarily related to biosolids) have been attributed. Tables 5-1 through 5-4 show the pathogens that have the greatest potential to be found in biosolids and that are currently pathogens of known health concern, and the diseases caused by the pathogens (U.S. Environmental Protection Agency 1985a, 1989a, 1989b, 1992a, 1992b, 1992c; Kowal 1985; Sorber and Moore 1987; Yanko 1988; Straub et al. 1993; ABT Associates 1993; National Academy of Sciences 1996; and Feachem et al. 1978). The tables do not list diseases that are unrelated to biosolids, which include toxoplasmosis (affects unborn fetuses, from cat feces, not many cases); polio virus, which no longer is a cause of disease in the Western Hemisphere; and cholera, which is rare. Also excluded was

Table 5-1.
Pathogenic Bacteria of Concern

Name	Disease	Nonhuman Reservoir	Density in Biosolids (no/gm/dry wt)	Survival Time (days)			Infective Dose (Numbers of Organisms)
				Soil	Crops	Surface Water	
Escherichia coli [pathogenic strains]	Gastroenteritis	Cattle		4-77	< 3 weeks	5-12	
Campylobacter jejuni	Gastroenteritis	Cattle, dogs, cats, poultry					—
Leptospira spp.	Leptospirosis (Weil's disease)	Domestic and wild mammals, rats		<15			
Salmonella (>2000 types)	Typhoid, paratyphoid, salmonellosis	Domestic and wild mammals, birds, turtles	3-103	11->259	2-53	<16	10^3-10^8
Shigella spp.	Bacillary dysentery		20	26-77	<2-8	1-<12	
Yersinia enterocolitica	Yersiniosis (gastroenteritis)	Wild and domestic birds and mammals	10^5				
Yersinia pseudotuberculosis	Yersiniosis (gastroenteritis)						
Mycobacterium	Tuberculosis			90-450	10-49		
					10->35	<6	
Background Indicators							
Total coliforms			100-10^6		6-35		
Fecal coliforms			100-10^6		< 56		10^6-10^8

Sources: Feachem et al. 1980, Kowal 1985, Yanko 1988, U.S. Environmental Protection Agency 1985a, Sorber and Moore 1987, EOA 1995, U.S. Environmental Protection Agency 1992c.

Table 5-2.
Pathogenic Viruses of Concern

			Survival Time in Days				
Name	**Disease**	**Density in Biosolids (No/gm dry wt)**	**Soil**	**Crops**	**Survival in Surface Water**	**Groundwater**	**Infective Dose (Numbers of Organisms)**
Enteroviruses (General)		0.2-210 (<2-0.8 MPN/mL liquid)	15-180	4-23	>188		
Coxsackievirus viruses (A & B)	"Flu-like symptoms"		Up to 180		5-33		1-10
Echovirus	"Flu-like symptoms"						1-10 (10-100PFU)
Rotavirus	Acute gastroenteritis	14-485					
Norwalk virus	"Flu-like symptoms"						
Adenovirus	"Flu-like symptoms"						
Reovirus	"Flu-like symptoms"						
Papovavirus	"Flu-like symptoms"						
Astrovirus	"Flu-like symptoms"						
Calicivirus	"Flu-like symptoms"						
Coronavrius-Like Particles	"Flu-like symptoms"						
Small round viruses (SRV)	"Flu-like symptoms"						
Other							
Hepatitis A	Hepatits					>490	1-10
Hepatitis B	Infectious hepatitis						
Hepatitus E	Hepatitis						

Sources: Feachem et al. 1980, Kowal 1985, Yanko 1988, U.S. Environmental Protection Agency 1985a, Sorber and Moore 1987, EOA 1995, U.S. Environmental Protection Agency 1992c.

Table 5-3.
Pathogenic Protozoans of Concern

Name	Disease	Nonhuman Reservoir	Density in Biosolids (no/gm dry wt)	Survival Time in Days: Soil	Crops	Surface Water	Infective Dose (Numbers of Organisms)
Human Pathogens							
Entamoeba histolytica	Amebic dysentery, liver abcess, colonic ulceration	Domestic and wild mammals		8	4	2-6	10 cysts
Giardia lamblia	Giardiasis (Diarrhea, malabsorption)	Pigs and other mammals, cattle, feral hogs, coyotes, squirrels, and rats	100-1000			>16	10-25 cysts
Cryptosporidium	Cryptosporidiosis (Diarrhea)	Cattle, feral hogs, coyotes, squirrels, and rats					
Balantidium coli	Mild diarrhea, colonic ulceration						10 cysts
Cyclospora Cayetamensis	Cyclosporiasis (Severe diarrhea)	None known					
Human Commensals							
Endolimax nana							
Entamoeba coli	Amoebic dysentery						
Iodamoeba butschlii							
Isospora hominis							
Animal Pathogens							
Eimeria spp.		Fish, birds, mammals					
Entamoeba spp.		Rodents, etc.					
Giarida spp.		Dogs, cats, wild mammals					
Isospora spp.		Dogs, cats					

Sources: Feachem et al. 1980, Kowal 1985, Yanko 1988, U.S. Environmental Protection Agency 1985a, Sorber and Moore 1987, EOA 1995, U.S. Environmental Protection Agency 1992c.

Table 5-4.
Pathogenic Helminths of Concern

Name	Common Name	Disease	Nonhuman Reservoir	Density in Biosolids	Survival Time (days) Soil	Crops	Surface Water	Infective Dose (Numbers of Organisms)
Nematodes (roundworms)								
Ascaris lumbircoides (ova)	Roundworm	Ascariasis		2-10	2-6 years	27-35	540	1 egg
Ascaris suum	Swine roundworm	Ascariasis	Pig*					1 egg
Enterobius vermicularis	Pinworm	Enterobiasis						
Trichuris trichiura (ova)	Whipworm	Trichuriasis		<1-3	>35	>18 months		1 egg
Necator americanus	Hookworm	Necatoriasis (anemia)			<4-6 months			1 egg
Ancylostoma duodenale	Hookworm	Ancylostomiasis (anemia)						
Ancylostoma braziliense	Curtaneous larva migrans		Cat, dog*					
Ancylostoma caninum	Dog hookworm	Cutaneous larva migrans	Dog*					
Stongyloides stercoralis	Threadworm	Strongyloidiasis	Dog		<35			
Toxocara canis	Dog roundwaorm	Visceral larva migrans	Dog*	<1				1 egg
Toxocara cati	Cat roundworm	Visceral larva migrans	Cat*					1 egg
Cestodes (Tapeworms)								
*Taenia saginata***	Beef tapeworm	Taeniasis					16-33	1 egg
Taenia solium	Pork tapeworm	Taeniasis, Cysticerosis						1 egg
Hymenolepis nana	Dwarf tapeworm	Taeniasis	Rat, mouse					1 egg
Echinococcus granulosus	Dog tapeworm	Unilocular hydatid disease	Dog*					
Echinococcus multilocularis		Alveolar hydatid disease	Dog, fox, cat*					

* Eggs not infective for man.
** Definitive host; man only incidentally infested.

Sources: Feachem et al. 1980, Kowal 1985, Yanko 1988, U.S. Environmental Protection Agency 1985a, Sorber and Moore 1987, EOA 1995, U.S. Environmental Protection Agency 1992c.

gastroenteritis (because of its general nature); AIDs because it is not associated with wastewater; and the fungal diseases, which are rare and not reported. Many more potential pathogens exist than are listed and, as noted above, new microbial pathogens are always being discovered.

Biosolids derived from the treatment of sewage sludge consist of a complex mixture of organic and inorganic compounds of biological and mineral origin removed from wastewater during primary, secondary, and tertiary sewage treatment (Straub et al. 1994). Properly treated biosolids meeting the pathogen-reduction and vector-control requirements of the EPA Part 503 regulations can still contain microorganisms that include bacterial, viral, protozoan, fungal, and helminth pathogens of potential concern to human and animal health (see Tables 5-1 through 5-4). The concern over any particular pathogen that may be present in biosolids is related to its ability to infect a host and cause disease. This ability depends on a wide variety of environmental factors (e.g., ability to survive wastewater treatment, longevity in the environment) and host-specific factors (sanitary habits, overall health, and any immune system impairments). Tables 5-1 through 5-4 list the specific disease organisms, diseases they cause, host organisms, and the infective dose (minimum number of organisms it takes to cause infection or induce illness) and provides other data on their measured concentrations in biosolids and viability in the environment (in soils, on vegetation, and in water). The listed pathogens can survive days (bacteria), months (viruses), or years (helminth eggs), depending on environmental conditions (Straub et al. 1994). The infective dose for some salmonella serotypes and other pathogenic bacteria is much higher than that of viruses and helminths and these organisms can multiply in high numbers when conditions are favorable (e.g., when a nutrient source such as a moist foodstuff is encountered). Viruses cannot multiply outside their hosts. The infective dose for *Salmonella sp.* varies by serotype and host factors.

Because individual pathogens cannot normally be detected or cannot be detected cost-effectively, indicator bacteria (such as the coliform group of bacteria) normally present in the human intestinal track are used as indicators of the presence of pathogens. For biosolids, the most favored group of indicators is *Salmonell*a, the most widely recognized enteric bacterial pathogen, with some 2,000 identified types. This species is responsible for some 1–2 million human disease cases a year in the United States (Straub et al. 1994). Fecal and total coliforms are normally used as indicators in wastewater and water samples and in contaminated soils.

It has been determined that the very young, the elderly, pregnant women, and the immunocompromised are at the greatest risk of serious illness and mortality from water and foodborne enteric microorganisms (Gerba et al. 1996). This segment of the population represents almost 20% of the population in the United States and is expected to continue to grow as the life span and number of immunocompromised individuals increases. It has been reported that half the documented deaths from gastroenteritis and hepatitis A illness in developed countries occur in the elderly and that the case fatality ratio for foodborne bacterial gastroenteritis outbreaks in nursing homes is 10 times greater than that for the general population (Gerba et al. 1996). Pregnant women also have a tenfold greater case fatality ratio than the general public from hepatitis E infection during waterborne disease outbreaks. Enteric diseases have their greatest impact on the immunocompromised, with *Crytosporidium* posing a particularly serious problem for AIDS (acquired immune deficiency syndrome) carriers. Cancer patients and transplant patients are also at greater risk than the population in general. Children are particularly affected by rotovirus.

As an example of the unavoidable uncertainty associated with the impacts from pathogens in biosolids, the authors of the study "Hazards from Pathogenic Microorganisms in Land-Disposed Sewage Sludge," explain the following:

> It should be recognized that the list of pathogens is not constant. As advances in analytical techniques and changes in society have occurred, new pathogens are recognized and the significance of well-known ones changes. Microorganisms are subject to mutation and evolution, allowing for adaptation to changes in their environment. In addition, many pathogens are viable but nonculturable by current techniques [cite], and actual concentrations in sludge are probably underestimated. Thus, no assessment of the risks associated with the land application of sewage sludge can ever be considered to be complete when dealing with microorganisms. As new agents are discovered and a greater understanding of their ecology is developed, we must be willing to reevaluate previous assumptions.

Emerging Pathogens of Concern

In most outbreaks of unknown cause or unknown source, a single or small list of organisms is normally suspected. If the causative agent is not identified or confirmed, it is because (1) the patient not seeking medical attention, (2) no laboratory diagnostic tests (including stool cultures and examination) are performed, and (3) either late or nonreporting of illnesses occurs that hinders the investigation of individual cases or outbreaks. Although most outbreaks are attributable to bacterial causes, limitations on our present diagnostic capabilities may also hinder a confirmatory diagnosis.   New techniques using genetic markers and electron microscopy have improved laboratory capabilities to detect and identify pathogens, particularly viruses. There continue to be numerous sporadic cases of diseases (particularly gastroenteritis) of unknown cause or unknown source that arise and may be associated with a number of agents or sources. A literature review of disease outbreaks on a worldwide basis was performed to determine some of the emerging pathogens and their modes of transmission. The results of this search are summarized in Appendix E. The results indicated that the reported cases are normally associated with poor sanitation, poor food preparation and handling practices, or drinking contaminated water. Information on emerging pathogens of concern (bacteria, parasitic microsporidians, viruses, and bovine spongiform encephalophathy) is presented in Appendix E. These are in addition to those pathogens such as E. coli O157:h7 and Cyclospora that which have caused several outbreaks in California.
In October 2003, CBS News carried a story on the potential health risks of Staphylococcus aureas (S. aureas) in Class B biosolids. The report recounted the story of a Pennsylvania teenager whose parents blame his death from a staph infection on his exposure to neighboring farm fields to which Class B biosolids had been applied. This followed a September 2002 story in USA TODAY which had cited studies by Cornell University's Waste Management Institute that concluded that there is a connection between illnesses and the land application of biosolids and by researchers from the University of Georgia in Athens that concluded that there is a substantial risk of illness in residents in areas near where biosolids are applied.

S. aureas is a commonly found strain of staph that resides in the human nose, skin, and gastro-intestinal tract and is present in raw sewage. It can cause a variety of human illnesses, including skin and wound infections, food poisoning, septicemia, pneumonia, and toxic shock syndrome.

A discussion of the epidemiology of potential S. aureas infections is outside the scope of this EIR. However, the two studies that were referenced in the 2002 USA TODAY story exemplify the concerns being raised. Researchers at Cornell's Waste Management Institute investigated numerous incidents where residents living near biosolids application sites reported illnesses. They compiled information from 39 reported incidents in 15 states affecting more than 328 people through interviews with individuals and information obtained from state health authorities and the U.S. EPA. Common symptoms included respiratory and gastro-intestinal disorders, skin diseases, and headaches (what the researches termed "sludge syndrome'). No testing was done of the sites from which the complaints arose. The study concludes that the amount of anecdotal evidence suggests that "contaminants coming from land application sites may pose an acute and immediate risk." The authors recommend better tracking of incidents and information sharing amount agencies, and a halt to the application of Class A and Class B biosolids to land pending definitive studies of the health effects. (Harrison. 2002)

The University of Georgia study interviewed 48 residents at 10 sites in the United States and Canada who had reported health problems they attributed to exposures to land-applied biosolids. They also reviewed the literature available on 5 other cases of illness. They found that interviewees commonly complained of irritation after exposure to winds blowing from fields to which biosolids had been applied. As with the Cornell study, no unexposed control group was included in the study. The University of Georgia study implicated biosolids in these illnesses, but concluded that it is "unknown, however, whether the strain(s) responsible for the infections had a common environmental source lasting for several years or if certain individuals or pets became persistent carriers and continued to expose others even after land application ceased." (Lewis. 2002)

While the above studies focused on anecdotal reports of illnesses, the University of Arizona National Science Foundation Water Quality Center reported in 2003 on its direct analysis of biosolids samples taken from 15 sites across the United States for the presence of viable S. aureas. These included 3 samples of raw, untreated sewage, 2 undigested primary sewage sludge samples, 23 different biosolids samples, and 27 aerosols obtained during the land application of biosolids. The sample sites were operating wastewater treatment facilities and agricultural lands where Class A and Class B biosolids were being applied in both the southwestern and northeastern United States. The analysis found S. aureas in samples of raw (untreated) sewage and undigested primary sewage sludge. However, no S. aureas was found in any of the samples taken from the land application sites, including airborne samples. The University of Arizona researchers concluded that "[t]hese results suggest that biosolids are not a significant source of S. aureas human exposure or source of S. aureas infection in humans." The researchers went on to raise a concern over studies of potential risk of illness that did not include "careful and rigorous confirmation steps for the identification of any bacterial pathogens." (Rusin. 2003)

Incidence of Biosolids-Related Illnesses

Years of study and review by health scientists from a wide variety of disciplines went into the development of the EPA's Part 503 regulations. Subsequent to the adoption of

Table 5-5.
Summary of Biosolids Land Application in California 1998
(Ranked by Order of Land Applied Biosolids)

County	Biosolids Land Application (dry tons/ year)	Permitted Acres[a]
Kern	148,000	50,528
Merced	60,000	26,807
Kings	60,000	17,529
San Diego	45,297	4,000
Riverside	34,800	18,954
Solano	30,000	23,055
Sacramento	23,601	1,264
Alameda	13,887	1,920
Sonoma	11,540	4,520
Tulare	10,438	656
San Joaquin	7,418	2,210
San Luis Obispo	2,890	25
Contra Costa	2,200	1,480
Shasta	2,000	–
Tehama	1,569	–
Fresno	895	3,693
Madera	800	–
Napa	700	–
Los Angeles	400	–
Humbolt	332	–
Santa Barbara	300	–
Placer	240	–
Tuolomne	200	–
Mendocino	200	–
Lassen	180	–
Calaveras	8	–
Totals	**457,895**	**156,641**

[a] Permitted acres estimated from March 1997 report by Ray Kearney (City of Los Angeles staff) and does not necessarily correspond to land application quantities.

Sources: California Association of Sanitation Agencies 1999; Fondahl, Brisco, and Thurber pers. comms.

these regulations, studies have continued to evaluate the potential impacts on public health from biosolids management practices. To date, there have been no reported incidences of human disease that is directly related to biosolids land application operations (National Academy of Sciences 1996). A single recorded case of beef tapeworm transmission through the fertilization of land with untreated sludge has been reported in the United States (Hammerberg et al. 1978).

If any association between biosolids use and illness exists, it may be evidenced in an increase in reported incidences of illness in the existing areas of heaviest biosolids application. Most of the pathogens of concern, particularly viruses, induce flu-like symptoms or cause episodes of gastroenteritis that are of short duration and are not life threatening. Generally, fewer than 5% of gastroenteritis cases are reported (Gerba pers. comm.); therefore, existing data will not provide conclusive evidence of the degree of such a relationship but may nevertheless provide useful information.

Information on the acreages of land-applied biosolids in California counties was compared with data on reported disease outbreaks to determine whether any relationship between biosolids application and reported illness in California can be inferred. Table 5-5 shows quantities of applied biosolids in 1998 by California county in rank order along with the estimated number of permitted acres on which biosolids could be applied. Those counties not shown had no reported application of biosolids (there may have been negligible quantities applied, but they were not included in the totals).

Data on the diseases of interest (those listed in Tables 5-1 through 5-4) were obtained from the Department of Health Services (DHS) (descriptions of the diseases of interest are provided in Appendix E). These data consisted of records on reportable diseases that are provided by local county and city health departments (Starr pers. comm.). The diseases for which data were obtained are those with causative agents that could be derived from biosolids; therefore, certain diseases that were rare, not reported, or not related to biosolids were not included (AIDS, fungal diseases, and nonspecific gastroenteritis). The DHS information consisted of 46,159 records representing 300,818 cases of disease and covering the period from 1990 though 1998 for some diseases and 1992 to 1998 for Enterotoxic *E. coli* O157:h7. The information was sorted by county, year, and disease (and broken down by pathogenic organisms) and is presented in Tables E-1a and E-1b through E-16a and E-16b in Appendix E for the number of cases and the incidence rate per 100,000 people by county and summarized on a statewide basis by year in Table 5-6. The summary data show that the number of cases of a particular disease and incidence rates vary from year to year as conditions favor its occurrence in a particular population.

The incidence of diseases presented on a statewide basis in Table 5-6 are shown by county for the past 6-9 years (depending upon when the reporting was started for a particular disease) in Tables 5-7 and 5-8. Also shown next to each county name (in parentheses) is the county's ranking in the state from the highest (1) to the lowest in terms of the amount of biosolids applied on land in that county in 1998. Table 5-7 contain a summary of the bacterial and viral diseases. Table 5-8 summarize the data on parasitic protozoan and helminthes diseases that are reported.

As noted in Table 5-5, the Central Valley counties of Kern, Merced, and Kings ranked first, second, and third in terms of the amount of biosolids that were land applied. The amounts applied were 32%,13%, and 13%, respectively, of the statewide total, or about 58% of the statewide total that was land applied.

The comparison of the number of reported outbreaks of acute infectious disease and the listing of counties where biosolids reuse occurs showed no apparent ~~correlation~~association between the highest biosolids use and any unusual illness outbreaks or patterns. Furthermore, discussions with public health officials and a review of available literature and discussions with other experts in the field revealed no reported disease problems associated with biosolids land application operations. Again, the types of diseases that might occur are not those that would normally be reported unless it was a severe case involving a visit to a doctor or hospital.

Non-Pathogenic Contaminants

There are non-pathogenic contaminants in biosolids that could contribute to degradation of water quality if not properly managed in accordance with existing regulations governing the disposal of biosolids and the use of best management practices. A wide range of contaminants were evaluated during the development of the Part 503 regulations governing biosolids disposal and beneficial reuse (U.S. Environmental Protection Agency 1992b, 1994, 1995). Among those constituents of particular concern are those that might contaminate sources of drinking water and result in impairment of beneficial uses, including uses for potable supplies, which would result in direct impacts on public health. Any such impairments in quality could indirectly affect irrigation and livestock watering and, hence, crop and animal health. Included among these contaminants are nitrates, certain trace metals, selenium, salts, trace SOCs, and a large number of other compounds (200 were initially addressed in the EPA 503 rule development). A brief summary of health concerns related to these contaminants follows.

Nitrates. Of the public health issues related to contaminants that may be present in biosolids and affect water quality, perhaps the most important is the potential contribution of nitrates to groundwater. The mechanisms of transport and general subject

Table 5-6.
Summary of Reported Infectious Diseases in California 1993-1998
(Years in which Data Were Available for All Diseases)

	Year						
Disease	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**Totals**
Amoebiasis	237	175	163	223	125	127	1,050
Campylobacteriosis	931	864	914	2,477	1,136	903	7,225
Cryptosporidiosis	90	155	199	166	62	75	747
Cryptosporidiosis (Type S)	50	18	13	3	42	16	142
Crytpossporidiosis Subtotal	140	173	212	169	104	91	889
Enterotoxic E-coli	0	3	2	33	8	9	55
Giardiasis	1,089	821	693	1,335	858	510	5,306
Hepatitis A	874	953	1,079	1,300	1,415	725	6,346
Salmonellosis	1,153	1,498	1,311	1,894	1,292	1,010	8,158
Shigellosis (Type A)	14	8	5	17	0	5	49
Shigellosis (Type B)	439	796	435	348	251	196	2465
Shigellosis (Type C)	29	2	45	32	30	23	161
Shigellosis (Type D)	682	469	873	625	388	397	3434
Shigellosis (Unidentified Type)	116	105	172	178	62	80	713
Shigellosis Subtotal	1,280	1,380	1,530	1,200	731	701	6,822
Tapeworm (Taenia)	2	6	5	0	1	14	28
Toxoplasmosis	42	9	28	23	18	9	129
Viral meningitis	425	181	119	188	186	403	1,502

Source: Starr pers. comm.

Table 5-7.
Summary of Reported Infectious Disease Cases (Bacterial and Viral) by County 1991-1998

Health Department Reporting[a]	Salmonellosis Six Year Totals	Campylobacteriosis Six Year Totals	Enterotoxic-E-coli Six Year Totals	Shigellosis Total for All Six Year Totals	Hepatitis A Eight Year Totals	Viral Meningitis Eight Year Totals
Long Beach (City)	508	442	6	620	874	300
Los Angeles (19)	6735	5306	33	5281	5934	1502
Pasadena (City)	143	131	1	144	150	28
San Francisco	8	21	1	389	151	
Alameda (8)	280	537	9	150	56	3
Amador	3	12			3	
Butte		1			1	
Calaveras (26)	5	11				
Colusa	3	2		2	4	
Contra Costa (13)	1				8	4
El Dorado	5			2	12	
Fresno (16)	7	15		18	18	13
Glenn	6	4			3	1
Humboldt(20)					6	
Imperial	40	19		43	27	3
Inyo	6	6		1		
Kern (1)					19	2
Kings (3)					4	
Lake	8	5			3	
Lassen (25)	4	4		2	1	2
Marin	35	167	1	15	1	7

Health Department Reporting[a]	Salmonellosis Six Year Totals	Campylobacteriosis Six Year Totals	Enterotoxic-E-coli Six Year Totals	Shigellosis Total for All Six Year Totals	Hepatitis A Eight Year Totals	Viral Meningitis Eight Year Totals
Mariposa	2	3			20	
Mendocino (24)	1	3			8	1
Merced (2)					14	
Modoc	1	3		2	1	
Monterey		2			1	3
Mono	16			1	15	
Napa (18)					2	3
Orange	159	160		43	180	187
Placer (22)	4	1			5	1
Plumas	6	2				
Riverside (5)					31	22
Sacramento (7)	2	86			38	11
San Benito	7	18	1	20	46	
San Bernardino	4	5		3	0	11
San Diego (4)	5	6	1	6	79	46
San Joaquin (11)					1	1
San Luis Obispo (12)	1				1	1
San Mateo					8	3
Santa Barbara (21)	1				2	
Santa Clara	2	3			19	3
Santa Cruz	60	100	1	28	13	11
Shasta (14)	6	9		3	13	
Sierra		1				
Siskiyou		13			4	

Health Department Reporting[a]	Salmonellosis Six Year Totals	Campylobacteriosis Six Year Totals	Enterotoxic-E-coli Six Year Totals	Shigellosis Total for All Six Year Totals	Hepatitis A Eight Year Totals	Viral Meningitis Eight Year Totals
Solano (6)					1	1
Sonoma (9)					7	1
Stanislaus					9	
Sutter					1	
Tehama (15)	5	2		1	3	
Trinity		3			1	
Tulare (10)	68	115	1	45	65	9
Tuolumne	11	7			1	1
Ventura				1	6	3
Yolo					1	
Yuba					3	1
Total Number of Reported Cases	8158	7225	55	6693	7874	2185

[a] All are county health departments except City of Long Beach and City of Pasadena.

Source: Starr pers. comm.

Table 5-8.
Summary of Reported Infectious Disease Cases (Parasitic, Protozoan, and Worm) by County 1991-1998

Health Department Reporting[a]	Cryptosporidiosis Total Eight Year Totals	Amoebiasis Six Year Totals	Giardiasis Six Year Totals	Toxo-plasmosis Six Year Totals	Tapeworm (Taenia) Six Year Totals
Long Beach (City)	77	91	671	6	
Los Angeles (19)	875	898	3832	121	26
Pasadena (City)	13	4	133	1	2
San Francisco	22	13	9		
Alameda (8)	1		152		
Amador			8		
Butte					
Calaveras (26)			12		
Colusa			2		
Contra Costa (13)			1		
El Dorado			1		
Fresno (16)	1		21		
Glenn			5		
Humboldt (20)					
Imperial			10		
Inyo					
Kern (1)	1				
Kings (3)					
Lake			14		
Lassen (25)			5		
Marin	3	30	75		
Mariposa		1	2		
Mendocino (24)			2		
Merced (2)					
Modoc			1		
Monterey	4				
Mono			1		
Napa (18)					
Orange	19	3	177		
Placer (22)			2		
Plumas			4		
Riverside (5)	1				
Sacramento (7)	1	6	63		
San Benito			6		
San Bernardino	3		5		
San Diego (4)	3		6	1	

Health Department Reporting[a]	Cryptosporidiosis Total Eight Year Totals	Amoebiasis Six Year Totals	Giardiasis Six Year Totals	Toxo-plasmosis Six Year Totals	Tapeworm (Taenia) Six Year Totals
San Joaquin (11)					
San Luis Obispo (12)	1				
San Mateo	1				
Santa Barbara (21)			1		
Santa Clara	1	2	1		
Santa Cruz					
Shasta (14)			4		
Sierra			1		
Siskiyou			3		
Solano (6)					
Sonoma (9)	1				
Stanislaus					
Sutter					
Tehama (15)		1	9		
Trinity			3		
Tulare (10)		1	59		
Tuolumne			5		
Ventura					
Yolo					
Yuba					
Total Number of Reported Cases	1028	1050	5306	129	28

[a] All are county health departments except City of Long Beach and City of Pasadena.

Source: Starr pers. comm.

of nitrates has been addressed in Chapter 3, "Soils, Hydrology, and Water Quality". Nitrates are relatively nontoxic to humans when ingested with water or food unless they are converted to nitrite, which can enter the bloodstream and bind with hemoglobin to form methemoglobin, a condition known as methemoglobinemia, which reduces the blood's oxygen-carrying capacity. The disease affects infants (generally those less than 6 months of age) because their gastric juices are more nearly neutral than those of adults (which have an acidic balance), resulting in nitrate reduction to nitrite being more prevalent. Methemoglobinemia is an extremely rare affliction with few reported fatalities. Only about 2,000 cases have been reported in the United States over the 30-year period since the disease was first reported (National Academy of Sciences 1988).

The EPA (in 1975) and the State of California (1989) have adopted drinking water standards of 45 mg/l (or parts per million [ppm]) nitrate (or 10 mg/l nitrate nitrogen) based on the first (1962) U.S. Public Health Service standard, which established 45 mg/l of nitrate in water as a warning level at which to avoid using water for feeding infants. Surveys of the scientific literature have found no cases of methemoglobinemia reported in the United States when water contained less than 45 mg/l of nitrate (10 mg/l nitrate nitrogen) (Winneberger 1982).

Another concern is the chemical reaction in which, under certain conditions, nitrate reacts with other compounds to form N-nitroso compounds, many of which are potent carcinogens. No health-related problems related to nitrates in biosolids were found during the literature review or discussions with health officials in California.

Metals. Health effects on humans associated with the presence of metals in water are addressed by the adopted water quality standards for surface waters and groundwater that protect the various designated beneficial uses. Health effects are avoided by the maintenance of water quality such that drinking water standards are not exceeded.

Selenium. Health effects resulting from selenium ingestion by humans are not well documented. The EPA risk assessment for land application of biosolids established the pollutant limits for selenium based on a child eating biosolids. The health effect resulting from exceeding the reference concentration for selenium is unknown. Studies of animals show that selenium can be lethal at high dosages and is a carcinogen in animals.

Salts. Increases in dietary salt in humans via water or foods are associated with an increase in heart disease, but the levels of concern and effects are still under debate.

Organics. Neither the EPA nor the SWRCB has placed limitations on the levels of SOCs in biosolids because SOCs were not found to pose a risk to health at the concentrations at which they are found in biosolids (U.S. Environmental Protection Agency 1995).

Endocrine Disruptors. The list of known and suspected hormone disruptors (pollutants with widespread distribution reported to have reproductive and endocrine-disrupting effects) include the following (after Colborn and Clement 1992, Colborn et al. 1993):

- Persistent organohalogens - dioxins, PCBs, furans, hexachlorobenzene,and pentachlorophenol
- Pesticides - 2,4,5-T,2,4-D, atrazine, benomyl, beta-HCH, chlordane, DDT and metabolites, endosulfan, lindane, heptachlor, h-epoxide, malathion, toxaphene, and many others
- Phenolic compounds - phthalates, such as di-ethylhexyl phthalate (DEHP), and many others
- Other organics - styrene dimers and trimers, benzo(a)pyrene
- Heavy metals - cadmium, lead, and mercury

All of the substances presently identified as hormone disruptors are now widely distributed throughout the environment, some are common constituents of consumer products, and many are now found in human tissues and have been shown to affect the health, reproduction, and behavior of animals.

Although trends in hormone-related diseases have not been clearly linked to environmental chemicals, it is probable that endocrine disruptors are contributing to human diseases and disfunction (Ankley et al. 1997). The EPA, through the 1996 reauthorization of the Safe Drinking Water Act, was directed to address possible endocrine disruptors in drinking water. The White House convened an interagency task force of national experts to improve the national response to the issue and evaluate consumer exposures, workplace exposures, and facility releases of chemicals, including the use of biosolids in land application (Ankley et al. 1997).

These “endocrine disruptors” include both natural compounds and synthetic chemicals. Some, called phytoestrogens, occur naturally in a variety of plants. Of current concern are the synthetic estrogens produced either through industrial manufacture or as byproducts of such processes or burning. Some of these have been found to speed the growth of cultures of breast cancer cells, raising questions about human health effects (Felsot 1994, MacMahon 1994, and Safe 1995). The effects have been detected at chemical concentrations of parts per trillion, levels at which most chemicals have never been tested.

Dioxins. Dioxins refers to a family of chemical compounds formed by the burning of chlorine-based chemical compounds. Dioxins occur commonly in the environment as a result of incineration and industrial practices. The most common health effect in people exposed to large amounts of dioxin is chloracne. Chloracne is a severe skin disease with acne-like lesions that occur mainly on the face and upper body. Other effects of exposure to large amounts of dioxin include skin rashes, skin discoloration, excessive body hair, and possibly mild liver damage. One of the main health effects in question for dioxins is the risk of cancer in adults. Several studies suggest that workers exposed to high levels of dioxins at their workplace over many years have an increased risk of cancer. Animal studies have also shown an increased risk of cancer from long-term exposure to dioxins. Finally, based on data from animal studies, there is some concern that exposure to low levels of dioxins over long periods (or high level exposures at sensitive times) might result in reproductive or developmental effects. (Interagency Working Group on Dioxin. October 2003)

Part 503 was promulgated in February 1993. EPA was required by a court order to promulgate a second round of Part 503 regulations by December 2001. Accordingly, the EPA conducted a screening for pollutants and concluded that the only pollutants posing a potential risk that were not regulated in the first round of regulations were dioxin and dioxin-like compounds. In late 1999, the EPA initiated a rulemaking to consider the regulation of the use and disposal of sewage sludge containing dioxins in biosolids. In the fall of 2003, after considerable research and risk assessment modeling, the EPA concluded that dioxins from biosolids do not pose a significant health risk to humans. The 2001 Dioxins Update to EPA's National Sewage Sludge Survey found that dioxin levels in treated sewage have declined since the last EPA survey in 1988.

The EPA's study considered those individuals most highly exposed to the dioxins (a theoretical farm family that applies sewage sludge to its land and whose members consume a high percentage of their own agricultural products) and found that only about 0.003 new cases of cancer would be expected each year, or 0.22 new cases of cancer over a lifespan of 70 years. The cancer risk to the general population would be even lower than this due to a lower exposure. As a result, on October 17, 2003 the EPA decided that no numeric limits or management practices for dioxin are required to adequately protect human health and the environment from the adverse effects of dioxins in land-applied biosolids. (EPA 2003) Therefore, no change to Part 503 resulted from this rulemaking.

Radioactivity in Sewage Sludge. The Sewage Sludge Subcommittee of the federal Interagency Steering Committee on Radiation Standards (ISCORS) issued three reports on this issue in late November 2003. ISCORS is made up of the EPA, Nuclear Regulatory Commission, Department of Energy, Department of Defense, Department of Transportation, Occupational Safety and Health Administration, and Department of Health and Human Services. Its purpose is to facilitate the coordination and resolution of regulatory issues associated with radiation risk to the public and workers, and the establishment of radiation standards. The Sewage Sludge Subcommittee was formed to examine the prevalence of radionuclides at publicly owned treatment works (POTWs) and the level of potential threat posed to human health and the environment by various levels of such materials, in response to a 1994 General Accounting Office Report that cited a number of cases where radionuclides were discovered in sewage sludge and ash.

ISCORS Assessment of Radioactivity in Sewage Sludge: Radiological Survey Results and Analysis summarizes the results of the testing of sewage sludge and ash from 313 POTWs around the country for radioactivity. The POTWs were selected for inclusion in the survey were those with the greatest potential for having detectable levels of radioactive materials. Samples from the POTWs were tested for both naturally-occurring and man-made radioactive materials. Naturally-occurring materials exist in soil and water and may enter a plant from industrial and water-treatment sources. Man-made radioactive materials typically enter a POTW through authorized releases allowed under federal or state license (most commonly medical diagnosis and treatment materials). The sample was intended to offer a snapshot of levels, not to characterize the sludge from any particular POTW. The authors concluded that the results of this non-random survey, of a limited number of POTWs, did not indicate that there is a widespread or nationwide public health concern. (Interagency Steering Committee on Radiation Standards. November 2003b.)

ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Address Radiation Doses, is a draft report assessing the potential levels of radiation doses to people by modeling seven scenarios for the movement of radioactivity from sludge into the local environment. Scenarios included residents of homes built on agricultural fields formerly applied with biosolids, residents of a town near fields where biosolids are being applied, workers at a POTW, and agricultural workers who operate equipment to apply biosolids to agricultural lands. The radionuclides modeled in this report were selected based on the results of the survey.

The preliminary conclusions of this report include the following:

- none of the non-POTW scenarios show a significant current widespread threat to public health;

- if agricultural land application is carried on for a long time into the future, then the potential exists for future radiation exposure of on-site residents, primarily due to Radon (50 and 100-year scenarios);

- when there are very high levels of radioactive materials, there is the potential for localized radiation exposure; and

- within a POTW, there is a potential for significant exposure of workers to radon when they are in the same room with large quantities of sludge and the room is small and poorly ventilated.

The report found that for both on-site residents and POTW workers, "exposure can be decreased radically through the use of readily available radon testing and mitigation technologies." (Interagency Steering Committee on Radiation Standards. November 2003a.)

ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works is a draft report recommending further actions that may be taken by POTW operators whenever elevated levels of radionuclides are detected at the POTW. While the document states that it does not constitute a rule making or formal guidance on this subject, it does offer a number of suggestions to POTWs relative to screening for the presence of radionuclides in the wastestream based on the presence of natural and man-made sources; consultation with federal and state agencies that regulate the release of radionuclides (for example, the California Department of Health Services' Radiological Health Branch); and actions reducing worker exposure. The authors of the report recommend using a threshold of 10 millirems/year or greater as the level of exposure that should trigger the POTW to consult with its state regulatory agency to determine if additional analyses should be conducted and responses need to be taken. (Interagency Steering Committee on Radiation Standards. November 2003c.)

The latter two reports are available for public comment until February 6, 2004.

Incidence of Chronic Disease in California Related to Non-pathogenic Contaminants

Diseases that are associated with general environmental exposure to toxic pollutants or other environmental contaminants are not well reported and the causes are difficult to pinpoint, even at some of the more infamous sites of exposure, such as the Love Canal in New York or other hazardous waste sites where high levels of contaminants can be found. At very low levels, such as those found in biosolids or in foods, the risks are measured in terms of a lifetime of chronic exposure. Such risk assessments have been performed by the EPA in support of the Part 503 regulations (Appendix E). No data are available that can be used to relate any type of biosolids-related exposure to any occupational or consumer-related exposure to chemicals that could be meaningfully interpreted. Further investigation would require an expenditure and work effort that are not warranted by the low risk reported by the EPA.

Routes and Pathways of Contact

Introduction

There are numerous pathways by which humans can come into contact with biosolids or biosolids-derived contaminants. These include direct contact or accidental ingestion, inhalation of biosolids-derived aerosols or dust, ingestion of water (surface waters and groundwater), and consumption of crops grown in biosolids-amended soils or of animals that have fed on crops grown in such soils. In addition, a variety of vectors can transmit pathogens (flies, mosquitos, fleas, rodents, or other animals than can transport the disease either mechanically or by biological processes) from biosolids to humans or intermediate hosts (Eastern Research Group 1992).

These various routes or pathways of contact can result in either acute or chronic disease if the exposure (dose) is high enough. For pathogens, the primary concern is acute diseases of a short-term duration (i.e., gastroenteritis or flu-like symptoms), while for the various potential chemical contaminants, risks are derived from chronic exposure via ingestion.

Pathogens that may be present in biosolids applied to land pose a disease risk only if there are routes of exposure that deliver an infective dose. The principal means of exposure is through ingestion or inhalation. Absorption through the skin is considered to be a minor route of exposure unless a field worker suffers a cut or other puncture to the skin and is exposed.

The EPA Part 503 regulations, which form a minimum set of standards for the regulation of biosolids in the GO, were developed after years of evaluation using various risk assessment methodologies (U.S. Environmental Protection Agency 1993). These methodologies focus on the various potential pollutants and the pathways that they might use to enter the human and animal diet. Risk assessments were not performed for the various pathogens, but risk management policies developed as part of the regulations assumed the use of technology and management practices to control pathogens (U.S. Environmental Protection Agency 1989a, 1989b, 1992c).

The scientific literature reviewed for this evaluation includes many general reviews and assessments of the environmental risks associated with various pathogens that may be present in biosolids (Feachem et al. 1978; Fitzgerald 1979; Little 1980; Clark et al. 1981; Kowal 1982, 1985; Sorber and Moore 1987; Scarpino et al. 1988; Dawson et al. 1982; and U.S. Environmental Protection Agency 1985b). Other risk assessments looked at bacterial and viral pathogens and how they might affect drinking water (Russin et al. 1997, Haas et al. 1993); in addition, Teunis and Havelaar (1996) assessed the risks for parasitic protozoans in drinking water. Adenovirus in wastewater was the subject of a risk assessment in 1997 (Crabtree et al. 1997) and rotaviruses and their risks were addressed in 1996 (Gerba et al. 1996).

Many other studies have been conducted to characterize the levels of chemical compounds found in biosolids (Kowal 1985; U.S. Environmental Protection Agency 1985b, 1990, 1992b) and the risks they might pose to human health using a deterministic point estimate approach to risk assessment. This approach looks at single values for input variables versus a range of input values (probabilistic approach using a Monte Carlo simulation), which some argue is needed (Harrison et al. 1999). Risk estimates based on ingestion of foods grown on biosolids-amended soils or consumption of meat from animals fed crops grown on biosolids-amended soils is an extremely challenging endeavor, given the wide range of variables that go into any risk assessment.

Direct Contact

The greatest direct exposure to biosolids is experienced by wastewater treatment plant operators and biosolids management facilities operating personnel. The greatest possible health risk associated with direct contact would probably involve a person having a cut or an exposed wound coming in direct contact with biosolids or contaminated operating equipment as the result of an unusual incident such as a fall or accident. Studies of the incidence of disease among wastewater personnel have indicated that they have no greater incidence of disease than the population in general (Clark et al. 1980, Cooper 1991). Farmers who have worked biosolids-amended soils have direct contact with biosolids and can get biosolids on their clothing. Studies have also been performed to compare the health of farm families from those farms using biosolids with the health of families on farms not using biosolids, and no health differences have been found (Dorn et al. 1985).

Pathogen Transport to Plants and Animals

When biosolids are applied to the land, pathogens that may be present in the biosolids can be deposited on plants, either directly from application operations or indirectly by vectors.

Virus transport from soil to plants has been suggested as a possible route of exposure, but no definitive research has shown this to occur (Straub et al.1993). Planting restrictions are applied on biosolids-amended fields to ensure that contamination of plants is minimized until die-off of any residual pathogens have occurred and risks are reduced. Animals could be harmed by biosolids-derived pathogens if they were exposed to a high density of pathogens. Typically, domestic animals are not present on the sites where biosolids are applied and the sites contain little wildlife because of the farming activity or other agricultural activities that occur make the environment less attractive as habitat. Grazing animals could be exposed to pathogens, but restrictions are normally placed on such activities to allow time for pathogens to reach very low densities by die-off.

Potential bacterial and viral pathogens carried by animals that could be contracted by humans include tuberculosis, salmonella, lysteria, campylobacter, rotovirus, and toxoplasmosis. More than 50 animals can carry *Cryptosporidium.* Rats and mice in particular are vectors for serious illnesses—for example, rodents may drink treated wastewater containing *Salmonella* from a local waterway, and the *Salmonella* could be transferred to chickens that eat rodent droppings incidentally, which then transfer the pathogen to humans through eggs (Kinde et al. 1996).

Transport on Crops, Equipment, or Clothing

Inanimate objects (such as crops, soil, equipment, and the shoes or clothing of workers) may be contaminated with infectious organisms that can be transported from sites of biosolids application. Restricting the harvesting of crops until natural die-off of remaining pathogens occurs, combined with good ~~sanitary~~sanitation practices and management practices for on-farm workers and biosolids transporters, has played a key role in minimizing the transport of pathogens offsite.

Vectors

Vectors are agents capable of transmitting a pathogen from one organism to another. Vectors can achieve this mechanically (simple transport by animals or insects such as flies) or biologically by playing a role in the life cycle of the pathogen (rodents). The traditional vectors are insects, particularly flies, but other vectors can include farm workers or biosolids workers who become ill and infect their families. Grazing animals can also be vectors. Parasite eggs from domestic animals have been demonstrated to have the ability to be transported by flies to grazing land and infecting livestock (Eastern Research Group 1992). Control of vectors has been an important element in the development of the Part 503 regulations (U.S. Environmental Protection Agency 1995, Eastern Research Group 1992), which include treatment and management practices that prevent conditions that attract vectors. Worker protection, good sanitation, and documentation of medical histories and sickness in workers' families can play an important role in preventing disease transmission should it occur.

Air Transport

Aerial dispersion of bacterial diseases such as tuberculosis, listeriosis, and legionnaires' disease have been documented (Szabo et al. 1982, al-Ghazali and al-Azawi 1988, Bigness 1999, and Rusin et al. 1997). Monitoring studies are limited, but studies indicate there is less risk associated with biosolids land application (unless it is a liquid spray operation) than with spray irrigation of wastewater which has not been disinfected. Studies of wastewater aerosol formation over a period of years showed little impact on air quality (Pahren and Jakubowski 1980). Studies in Texas showed that bacterial levels were highest around the sludge mixing and loading facilities where agitation occurred and showed that normal heterotrophic bacteria were present in air, but there was an absence of Salmonella, fecal coliforms or coliphages (Pillai et al. 1996) Pathogenic *Clostridia* were detected where physical agitation occurred. These researchers recommended wearing masks to minimize risk to operators. Monitoring of coliphage and enteroviruses in sewage and air adjacent to an activated sludge plant showed that coliphages were not necessarily a good indicator of enteroviruses (Carducci et al. 1995). This points out the difficulties in finding suitable indicators for environmental monitoring.

Dust and fine particles that can be inhaled and reach the deepest parts of the lung are of particular health concern. These fine particles (referred to as PM10) have been regulated for at least ten years with both federal and state standards (See Chapter 10). Also regulated are air toxics at both the federal and state level.

Measurements of bacteria in the air downwind of biosolids processing or application sites is limited (Pillai et al. 1996) and the data collected shows the presence of high numbers of bacteria when there is mixing or dispersal (like a manure spreader), but the risk of an infectious dose of a pathogenic bacterial species in an outdoor area appears to be negligible (Pillai et al. 1996). No reported cases of bacterial or viral illness derived from such an occurrence were found during the literature review including the work of Pillai et al. (1996).

There have only been a few reported cases of biosolids-related illnesses as a result of airborne transmittal of pathogens (see aspergillus discussions in this chapter). Nethercott (1981) reported illnesses from sludge incinerator dust, but this pathway is not applicable to this project. Most of these incidences are related to work in confined spaces such as sludge dewatering facilities, composting facilities (Clark et al. 1983, Millner et al. 1980), or processing facilities and not related to the transport, unloading or application of biosolids.

There have been reported cases of fungal allergies and possible outbreaks of asthma near composting operations that have generated large populations of *Aspergillus fungi* which thrive in the environment created during composting (Kramer 1992). Studies of composting operations and at farms where biosolids have been used show no unusual health effects compared to farms where no biosolids were applied (Dorn et al. 1985). These fungi are found everywhere where the right conditions exist (compost piles, wood chip piles, potted plants), not just in biosolids operations (Raper and Fenel 1965).

Those at risk in the areas immediately adjacent to such operations are immunosuppressed people such as organ transplant recipients, and people with cancer, AIDS, or leukemia (Rosenberg and Minimato 1996, Ampel 1996). Such operations have been regulated such that setbacks and restrictions on dust generation have been placed on them by the California Integrated Waste Management Board.

Transport of bacteria, viruses and other pathogens by air or by aerial vectors such as insects and birds has been hypothesized.

No reported cases of air-borne transmission of disease have been documented in California as it relates to biosolids management although the potential exists.

Groundwater Transport

When biosolids are applied to the land surface, the particulates in biosolids typically combine with soil material to form a filter mat so that primarily, soluble and colloidal particles enter the soil. Larger organisms such as protozoans and helminth eggs are retained in the upper soil layers, while virus particles and small bacteria can be transported through the soil to groundwater. As discussed in Chapter 3 and Chapter 4, the mechanisms of pathogen removal in soil are primarily filtration (affects bacteria) and adsorption (for viruses).

Coarse sands and soils with gravel lenses are those most conducive to pathogen transport to groundwater (Kowal 1985, Woessner et al. 1998). Most other soils, particularly fine-grained soils, are effective at removing both bacteria and viruses. The most important consideration after the soil type is the depth to groundwater and proximity to wells used for water supplies, particularly those serving as drinking water which is not subject to treatment and disinfection after it is extracted. The separation between water supply sources and wastewater management facilities using setbacks has been an effective means of protecting public health and relying on the natural filtering qualities of soils.

As described in Chapters 3 and 4, the study of the movement and transport of bacteria and viruses in soils and the transport to groundwater has been the subject of many studies. Most often these studies have focused on viral transport (or coliphage, viruses that are in bacteria) from wastewater and use tracers to simulate viruses due to the difficulty in obtaining permits to actually release viruses into the environment (McKay and Cherry 1993). The difficulty in such studies is the low concentrations that must be detected. Large amounts of water must be filtered to obtain a measurable amount of viruses in groundwater. Generally, this means that it would be extremely hard to obtain an infectious dose due to the large amounts of water that would have to be consumed. Studies on the transport of most viruses at biosolids land application sites has shown that adsorption and/or filtration have reduced viral density and prevented it from reaching groundwater (Straub et al. 1994). However, further research is needed due to the variety of viruses, differing soil conditions, and different climatic regimes. A typical maximum survival time for viruses in soil (at very low temperatures) is 170 days (Kowal 1985) (see Table 5-2) and the maximum distances traveled, even in sandy soils the is about 2 feet per day when a site is under intense recharge (Gerba et al. 1991). Only in instances where there has been significant contamination under unusual circumstances (fractured rock or very porous soils allowing wastewater from a septic tank to reach a drinking water well for example, such as occurred in an outbreak of gastroenteritis in 1991 [Lawson et al. 1991]) is it likely that viruses can pass through most soils to reach potable groundwater (Woessner et al. 1998). Setback and minimum distances between wastewater disposal or biosolids disposal operations and potable wells have been used to provide for safe management of human wastes. There have been no instances in the literature reviewed where biosolids land application has resulted in the measurable contamination of groundwater with pathogens that have contributed to an outbreak of disease.

Surface Water Transport

As discussed in Chapter 3, biosolids application has the potential to contribute to surface runoff and transport potential contaminants to local surface waters. Washoff into surface waters used for irrigation, stockwatering, potable supplies or recreation are all possible modes of exposure under extreme conditions, such as flooding during a high-intensity storm. The potential pathogens and diseases they cause have been discussed. Survival in surface water of various pathogenic microorganisms was presented in Tables 5-1 through 5-4 and indicate relatively short survival times compared to survival in groundwater. Risk assessments of virus in drinking water (Haas et al. 1993) and water (Crabtree et al. 1997 and Gerba et al. 1996) and other microbial risk assessment models (Teunis and Havelaar 1996, EOA 1995) have been evolving and refined to better estimate risks associated with various pathogens. Most of these efforts to conduct risk assessments have been limited to use with water because of the higher degrees of exposure that people have to water and the simple fact that there are disease outbreaks attributable to waterborne pathogens. No such outbreaks have been recorded for biosolids, so little attention has gone into the development of models for pathogen risk in recent years. Proper site management can preclude washoff of pathogens and particulates.

Potential Health Effects from Direct Ingestion or Intake ~~via~~of Foods Related to Biosolids

Health effects from contaminants that may be present in biosolids and have been found to be of human health concern (and thus have regulatory limits based on human health concerns) due to ingestion of foods grown in biosolids-amended soils or from direct ingestion (children less than 2 years of age) of biosolids are summarized in Table 5-9. Most of these health effects are uncommon and most have been noted in the literature when there is some form of severe contamination of food supplies by hazardous wastes, toxic chemicals, or industrial contamination from chronic discharges prior to implementation of pollution control regulations. All of these contaminants and many others have been addressed or are being addressed in on-going regulatory control programs to update or develop new standards for protecting public health. Development of the 503 regulations involved an extensive review of individual pollutants and the use of hazard indices and assessment of worst case exposure conditions to develop numerical limits for biosolids that would assure protection of public health under proper management conditions (U.S. Environmental Protection Agency 1985). Such standards include those related to drinking water, surface water, groundwater, food safety, fertilizer quality, consumer products, air quality, and biosolids through the 503 regulations development.

The health risks from biosolids land application were found to be the highest for a child directly ingesting biosolids for several of the trace metals (Pathway 3 for arsenic, cadmium, lead, mercury, and selenium) (see Appendix E, Part 2). For other regulated compounds, phytotoxicity was found to be the limiting pathway (chromium, copper, nickel and zinc). Molybdenum was limiting due to animal health concerns from consuming biosolids-amended feed. The reduction in risks to humans occurs as a result of the soil-plant barrier concept (described by Chaney 1980) which shows that if plants and/or animals are protected against toxicity from biosolids-applied metals (through natural processes), then humans are protected (plant phytoxicity would occur and thus it would not grow and be consumed or there would be less consumption because of reduced plant yield). For some conditions, risks from excessive selenium, molydenum and cadmium would not be prevented through this mechanism. However, antagonistic effects from zinc, calcium and iron present in biosolids and the soil may counteract toxic effects by acting to inhibit absorption in animals (U.S. Environmental Protection Agency 1995a).

Table 5-9. Chronic Human Health Effects Associated with Regulated Contaminants Found in Biosolids

Contaminant	Health Effects	Exposure	Environmental Fate
Lead	Permanent neurological damage; endocrine system disruption	Mainly from fruits and grains, deposition from air to plants, livestock, children ingesting soil or biosolids	No known safe level persistent
Cadmium	Cancer, kidney disease, neurological disfunction, fertility problems; immune system changes; birth	Defects mainly through food, children ingesting soil or biosolids	Persistent, bioaccumulative
Dioxins	Cancer, endocrine disruption, immune system damage; negative effects seen at levels as low as ppt	Mainly through meat and dairy consumption	Persistent, bioaccumulative
Mercury	Neurological disfunction	Mainly through fish and food consumption	Persistent, bioaccumulative
Selenium	Toxicity in humans is rare, most effects in grazing animals	Children ingesting biosolids	Persistent, bioaccumulative
Arsenic	Malaise, fatique, gastrointestinal disturbances; peripheral neuropathy	Children ingesting soil or biosolids	Persistent, bioaccumulative
Salts (sodium)	Chronic effects such as carbiovascular	Water supplies, excessive intake in foods	Persistent
Nitrate	Methemoglobanemia	Contaminated groundwater	Persistent
Organics	Acute toxicity; hypersensitivity mutagenesis; carcinogenesis; other chronic effects[a]	Children ingesting soil or biosolids, consumption of contaminated food and water supplies, breathing air in confined biosolids processing areas	Persistent, bioaccumulative
Endocrine disruptors[c]	Breast cancer? teratogeneis?[b]	Contaminated food	Persistent

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[a] Chronic effects could include those that are cardiovascular, immunological, hematological, neurological, etc.
[b] Alleged, not demonstrated.
[C] See listings and discussion in Appendix PE (Part 3) for more information.

Sources: Information from Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, and U.S. Environmental Protection Agency accessed on Centers for Disease Control Web page (Centers for Disease Control 1999).

The National Research Council also completed an independent study for the EPA that was released in July of 2002. Although this study recommend further research on the topic, it also stated that there is no documented scientific evidence that land application of biosolids pose any human health risk. This study reviewed the risk-assessment methods and data used to establish concentration limits for chemical pollutants in biosolids, reviewed the current standards for pathogen elimination in biosolids and, explored whether pathogen risk assessment can be integrated with chemical risk assessment (National Resources Council 2002).

There is increasing attention being given to the endocrine disruptors as discussed above under water and further in Part 3 of Appendix E. There are a number of chemicals used in agriculture (pesticides) and compounds which may be present in biosolids which are listed as suspected endocrine disruptors which are widespread in the environment. Actual effects on health from environmental levels of these compounds is still an area of controversy and direct links have yet to be established between chemicals and human health effects.

Regulatory Setting

The basic standards for the protection of public health from the land application of biosolids are the EPA's regulations adopted in February 1993 which are contained in 40 CFR 503 commonly referred to as the 503 regulations. These regulations establish ceiling concentrations for metals and pathogen and vector attraction reduction standards; management criteria for the protection of water quality and public health; and annual and cumulative discharge limitations of persistent pollutants, such as heavy metals, to land for the protection of livestock, crop, and human health and water quality protection. These criteria are based on a risk-based evaluation using 14 different pathways of potential exposure for humans and animals (see Appendix E, Part 2 for identification of the various pathways and the criteria used). The 503 regulations form the basic minimum standards contained in the GO being addressed by this EIR.

In addition, there are numerous Federal and State laws and regulations which apply to various aspects of the transport and distribution of biosolids for land application and govern all aspects of the operations involved in land application. A general discussion of key regulations governing the protection of public health is presented below. Details can be found in the various statutes. All of these laws and regulations are enforceable by various local, state and federal agencies charged with administering them.

Waste Discharge Requirements

See “State Programs—Role of RWQCBs” in Chapter 2, “Program Description”, for a discussion of WDRs.

National Pollutant Discharge Elimination System Permits

All wastewater agencies that discharge effluent to the surface waters of the United States are issued NPDES permits by one of the RWQCBs under a program approved by the EPA and delegated to the State of California under provisions of the federal Clean Water Act.

Each NPDES permit contains a monitoring and reporting program that identifies the volume of solid material removed from the wastewater and the locations where this material was taken, including biosolids. The NPDES permit also requires periodic sampling of biosolids for priority pollutants and other constituents of concern in accordance with the provisions of the EPA Part 503 regulations.

California Hazardous Waste Control Law

In accordance with the California Hazardous Waste Control Law (HWCL), the California Department of Toxic Substances Control (DTSC) is responsible for determining whether sewage sludge/biosolids are a hazardous or nonhazardous material according to CCR Title 22, Article 11. Title 22 defines “sludge” as “any solid, semisolid, or liquid waste generated from a municipal, commercial, or industrial wastewater plant . . . exclusive of treated effluent from a wastewater treatment plant”.

The DTSC uses various adopted criteria to determine whether a sludge is classified as a hazardous waste; these include testing for toxicity, persistent and bioaccumulative toxic substances, ignitability, reactivity, and corrosivity. Any waste that contains a substance that exceeds either a listed soluble threshold limit concentration (STLC) or a listed threshold limit concentration (TLC) is deemed a hazardous waste. Most municipal biosolids are classified as nonhazardous. Determining whether a particular biosolids product is hazardous is a key step in identifying available disposal and reuse options. If a sludge or biosolids product is hazardous, then the GO would preclude its application to land and may require the issuance of a Hazardous Waste Facilities Permit by the DTSC for certain operations.

Discharge of Waste to Land

The SWRCB administers CCR Title 23~~, Division 3, Chapter 15~~ and CCR Title 27 (Discharges of Waste to Land), which govern~~s~~ the disposal of wastes in a landfill or on dedicated land disposal sites. ~~Chapter 15~~ These regulations require~~s~~ that all wastes be classified to determine the appropriate type of waste management strategy to be used. As mentioned above, classification of materials as hazardous or nonhazardous is the responsibility of the DTSC. However, the SWRCB and its nine RWQCBs may further classify DTSC nonhazardous waste, such as wastewater sludge, as a designated waste. The solids content of nonhazardous sewage sludge determines the type of landfill that can be used for disposal. The ~~Chapter 15~~Title 27 regulations also address the use of dried sewage sludge as daily landfill cover. RWQCBs play a role in issuing WDRs or waivers for land application sites, inspecting and monitoring such sites, and providing enforcement, as necessary. Any sewage sludge or biosolids that are not suitable for land application under the provisions of the GO and, hence, earmarked for disposal would be subject to provisions of ~~Chapter 15~~Title 27 or further treatment, which could trigger additional requirements, such as compliance with regulations for composting operations.

Regulatory Requirements for Composting Operations

The IWMB administers solid waste regulations set forth in CCR Title 14 that pertain to composting operations and facilities. Title 14, Chapter 3.1, Composting Operations Regulatory Requirements, apply when biosolids are mixed with chipped green waste for composting. These regulations specify permitting, siting and design, operating standards, sampling requirements, metal concentrations, and pathogen reduction standards. IWMB regulations are implemented through its local enforcement agencies (LEAs), which issue solid waste facilities permits (SWFPs) for composting and dedicated disposal sites.

Source Reduction and Recycling

IWMB staff members oversee source reduction and recycling efforts of jurisdictions throughout California in accordance with Public Resources Code Section 40000 et seq.~~,~~ ~~which implements Assembly Bill 939 (AB 939) legislation.~~ Under Section 41750, cities and counties were required to begin planning to achieve solid waste reduction immediately to manage remaining landfill space in an effective and environmentally sound manner. Section 40191 defines "solid wastes" as "all putrescible and non-putrescible solid, semisolid, and liquid wastes excluding hazardous waste". Solid wastes by this definition include dewatered, treated, or chemically fixed sewage sludge.

~~AB 939~~Starting with Section 41000, the CCR mandates the use of source reduction, source separation, diversion, recycling, reuse, composting, and co-composting of solid waste to the maximum extent feasible to conserve water, energy, and other natural resources and to protect the environment. ~~AB 939~~Section 41780.2 require~~d~~s jurisdictions to divert 25% of their generated waste by 1995, increasing to 50% by the year 2000. For many jurisdictions in California, land application of biosolids serves as a means of achieving these diversion rates.

Safe Drinking Water and Toxic Enforcement Act (Health and Safety Code Section 25249.5)

Perhaps the most important long-term regulatory standards that govern biosolids are the Safe Drinking Water standards that apply to both surface and groundwaters which are used for public water supplies. Groundwater quality protection is one of the key areas of concern and the GO contains a prohibition against causing these standards to be exceeded as a result of biosolids land application.

Ambient Water Quality Criteria for the Protection of Human Health

For information on ambient water quality criteria, see Chapter 3, "Soils Hydrology, and Water Quality".

Ambient Air Quality and Air Toxics

There are no state policies or regulations that specifically address air quality issues related to biosolids land application. There are numerous state and local air quality regulations that govern compliance with transportation-related source emissions (from hauling equipment and incorporation equipment) and general provisions related to compliance with local air quality management district regulations for ambient air quality and specific source control which might have been adopted with regard to toxic air emissions. The federal and state ambient air quality standards of greatest concern with respect to land application of biosolids are the particulate matter standard for fine particulates (PM10). For more details see the air quality chapter (Chapter 10).

State Health and Safety Code and California Food and Agricultural Code

The California State Codes (Health and Safety, Title 22) and California Food and Agricultural Code contain numerous provisions related to public health and safety which would apply to farming operations that land apply biosolids. These provisions relate to water supply protection, sanitation, sewerage, and general sanitation and crop harvesting as well as pesticide residues and handling of toxic materials. All of these provisions are in addition to all the requirements contained in the GO related to protecting water quality.

Biosolids may contain toxic pollutants (heavy metals, organics, and inorganic compounds) and other chemicals (such as minerals and nutrients) which may be subject to regulation under one or more State laws or regulations governing hazardous materials (if concentrations were high enough). Biosolids that meet the 503 requirements are not subject to hazardous waste regulations because the maximum concentration levels (ceiling levels) are below the levels that would result in the material being classified as a hazardous waste. Section 14505 of the California Food and Agricultural Code classifies soil amendments derived from municipal sewage sludge as fertilizing material which is exempt from hazardous waste regulations. New studies are underway to assess the health hazards associated with different materials used in the manufacture of soil amendments that will further restrict and perhaps set numerical standards for fertilizers.

~~OSHA/CalOSHA~~California Occupational Safety and Health Act Requirements

Worker safety is governed by the provisions of the California Occupational Safety and Health Act. These regulations govern workplace safety and health hazards for such things as exposure to hazardous chemicals and substances, excessive noise, and unsafe work conditions. These provisions apply to employers and are designed to provide a safe and healthy work environment.

Food Safety

The California Department of Food and Agriculture (CDFA) has started an open, facilitated process to develop regulations covering heavy metals in commercial fertilizers, biosolids, non-hazardous ash, and other soil amendments. This work is being done in conjunction with the University of California and will focus on both inorganic and organic fertilizers. The process will continue over the next year. The results of this effort will be reviewed by the SWRCB and adjustments in the proposed GO could be made if necessary to protect food safety.

There are numerous food safety and quality laws which apply to the quality and handling of foods which will apply to the growers using biosolids as a soil amendment. These are not part of the GO which addressed only water quality protection. These regulations include but are not limited to the following:

- Organic Foods Production Act of 1990
- Federal Food, Drug and Cosmetic Act (21 U. S. C. 301)
- ~~Sanitary~~Sanitation Food Transportation Act of 1990 (governs transportation of food products)
- California Uniform Retail Food Facilities Law (CURFFL; Health and Safety Code Sections 27500 et seq.)
- Inspection and certification of fresh fruits, vegetables and other processed foods (7 CFR 51-75P)
- Containers and their inspection (7 CFR 42)

- Food Processing (21 CFR 100-199)
- Labeling, standards of quality and contaminants (21 CFR 109)
- Good Manufacturing Standards (21 CFR 110)
- Enforcement policies (21 CFR 7)
- Production process and use of additives (21 CFR 184-186)
- Prohibited substances (21 CFR 186-189)

- California Health and Safety Code, Division 105, Part 5 (Sherman Food, Drug, and Cosmetic Law)

Note that uncooked food sold by retail establishments and food consumed at home by the public is not directly protected by the Model Food Code, which incorporates the latest and best scientifically based advice for preventing foodborne illness. This Code is used by local and state agencies responsible for inspecting and enforcing safe food handling practices at the retail level.

Also, it should be noted that neither the USDA nor the FDA have specific regulations for the use of biosolids in food production, but rely on existing regulatory programs involved with the consumption of animal products and foods that are commercially processed (general health and safety laws governing water and food sanitation) (National Academy of Sciences 1996).

Impacts and Mitigation Measures

The following public health impact analysis focuses on the potential for human contact with the pathogens and contaminants known to occur regularly in biosolids in the United States. The number of known foodborne and waterborne pathogens appears to be on the increase as new techniques are developed to detect previously unknown species. No information exists at this time indicating that any of the emerging pathogens pose any greater risk to the public than those that were considered during development of the Part 503 regulations and establishment of mandatory management practices to control pathogens and vectors. Furthermore, there is no indication that there is any more risk associated with biosolids than with other sources of these pathogens. To date, outbreaks of diseases have been associated with undercooked food, fecal-oral transmission, poor food handling practices and sanitation, and inadequate sewage facilities or water management at specific properties. Biosolids are generated under controlled and monitored conditions in a highly regulated environment.

Some pathogen-related issues will have to be addressed on an ongoing basis as more is learned about the presence and fate of disease-causing organisms referred to as "emerging pathogens", which are newly discovered or have new characteristics that make them of greater concern (e.g., antibiotic-resistant strains). Also of concern are possible effects on immunocompromised populations (particularly people with acquired immunodeficiency syndrome), which might have the potential for increased exposure, under certain unusual circumstances, to pathogens such as *Giardia* and *Cryptosporidium* that may be present in contaminated surface water supplies. Research on methods of detecting the pathogens responsible for emerging diseases and systems of reporting unusual outbreaks (Centers for Disease Control 1999) will have to be relied upon to guide health and regulatory officials toward appropriate regulations and preventive measures to keep disease outbreaks from occurring. Efforts are continuing for better ways to detect the presence of pathogens in wastewater, sludge, and biosolids (Water Environment Federation 1999). To date, no significant outbreaks of infectious disease have been associated with biosolids land application practices (Bastian, Starr pers. comms.).

Approach and Methods

The public health impact analysis presented below has been coordinated with other technical analyses (those for water quality, air quality, and land productivity) to determine the likelihood of the presence of pathogens or other constituents of concern in land-applied biosolids and the potential for their transport to human receptors. It was assumed for this assessment that any biosolids to be land applied or used for other purposes allowed under the GO would meet the minimum requirements of the EPA Part 503 regulations and the additional restrictions contained in the GO.

Impacts on public health that could result from land application of biosolids are difficult to quantify because of the difficulty of establishing a clear relationship between human exposure to pathogens or chemical contaminants and reported illness in humans. EPA undertook extensive efforts to evaluate potential disease risks associated with biosolids disposal and reuse practices in support of the development of the Part 503 regulations. The numerical limitations and management practices (for pathogens) specified in the Part 503 regulations were derived as a result of extensive scientific studies, reviews of scientific literature, collection of nationwide data on biosolids quality and experiences related to biosolids reuse, epidemiological studies, detailed risk assessments for each of the regulated constituents and many others (some 200 chemicals initially), and field studies to quantify the concentrations and environmental fate of pathogens and chemical contaminants in biosolids.

This assessment relies on all those studies and the EPA Technical Support Documents prepared for the Part 503 regulatory program. EPA's information was used to establish a baseline for identifying impacts in this analysis and to determine relative risks to individuals from biosolids reuse practices. Additional research was conducted to identify conditions specific to California, including disease incidence and physical (soil and hydrologic) conditions not anticipated in the Part 503 regulations. The analysis also assumes "worst-case" conditions, such as the use of Class B biosolids (with a higher allowable pathogenic microorganism content) and the maximum allowable application and cumulative loading rate (up to the limits allowed in the 503 regulations and GO).

Conclusions regarding the potential for impacts were drawn based on best professional judgment, given the available information and assuming worst-case conditions. The quantitative risk assessments performed by EPA (U.S. Environmental Protection Agency 1995) and others (Scarpino et al. 1988, Rusin et al. 1997, ABT Associates 1993), combined with reviews of the literature used to support the development of the Part 503 regulations, new scientific literature published or made available since 1995, and personal contacts with experts and officials around the state and elsewhere, were used in support of this impact assessment. The significance of potential impacts was evaluated based on the available data on the potential extent, duration, frequency, and intensity of effects.

The evaluation of impacts is supported by the information provided above under "Environmental Setting" and in Appendix E, which is referenced as necessary to support the environmental determinations.

Thresholds of Significance

According to thresholds established by existing public health regulations (federal, state, and county), a project may result in a significant impact if it would:

- create a public health hazard or involve the use, production, or disposal of materials that pose a hazard to people or to animal or plant populations in the area affected;
- violate federal, state, or local criteria concerning exposure to biosolids-derived contaminants or pathogenic microorganisms (including the Safe Drinking Water Act, federal Occupational Safety and Health Administration workplace standards, food safety laws, and other public health criteria); or

- violate any ambient air quality standard, contribute substantially to an existing or projected air quality violation, or expose sensitive receptors to substantial pollutant concentrations.

Impacts of Agricultural Use

Impact: Potential for Increased Incidence of Disease Resulting from Direct Contact with Pathogenic Organisms at Biosolids Land Application Sites

Under the GO, land application of biosolids could increase from 456,040 dry tons per year in 1998 to 576,690 dry tons per year in 2015 as the state's population increases and levels of wastewater treatment are improved. The amount of land on which biosolids are beneficially used is likely to increase, resulting in an increased probability of humans coming in direct contact with biosolids. Although it has been demonstrated over the years that anaerobic digestion is effective at reducing bacterial hazards associated with biosolids, concerns still exist over the survival of viruses or pathogens that encyst (such as *Cryptosporidium*, or *Ascaris* ova) and that could be transmitted to humans through direct contact.

Those people with the greatest potential for direct exposure to biosolids are equipment operators at wastewater treatment plants and land application sites, and farmworkers. Individuals in these categories could also cause incidental exposure of their families to biosolids if they carry biosolids home on their shoes and clothing. Risks to the general public also could increase as a result of increased exposure if land application activities occur at sites accessible to the general public.

The issue of the survival in biosolids of viruses or pathogens that encyst and their potential transmission to humans was reviewed by a panel of experts convened by the National Research Council and discussed in its report "Use of Reclaimed Water and Sludge in Food Crop Production" (National Academy of Sciences 1996). The panel noted, "There have been no reported outbreaks of infectious disease associated with a population's exposure—either directly or through food consumption pathways—to adequately treated and properly distributed reclaimed water or sludge applied to agricultural land." The report also noted that because there are many sources of infectious disease agents other than reclaimed water or biosolids used in land application, such as prepared food and person-to-person contact, the potential added exposure to pathogens resulting from the proper recycling of these materials is "minuscule compared to our everyday exposure to pathogens from other sources".

The issue of microbiological risks from contact with biosolids remains controversial, however, in part because epidemiologic evidence is very difficult to compile and any association between health problems and biosolids application (or other environmental exposure) is extremely difficult to document. Considering the concentrations of long-lived encapsulated forms of certain pathogens (such as *Giardia*, *Crytosporidium*, and *Ascaris*) that have been found in biosolids, it may be assumed that some risk to farmworkers and others working closely with biosolids will always exist. An infectious dose could be as low as one ovum for *Ascaris* and, although their viability remains in question, ova are found at concentrations in digested sludge of 2-10 per gram of dried biosolids. One would have to ingest only a small quantity of biosolids to get such a dose; however, the low probability of adult ingestion of biosolids must be taken into consideration as well.

The available data on workers exposed to biosolids do not support a conclusion that direct exposure to biosolids increases health risks. Wastewater treatment plant personnel, the workers having the greatest occupational exposure to biosolids, have been found to have no greater illness rates than the general public (Clark et al. 1983). To date, compost workers are the occupational group for whom the most evidence of potential effects from biosolids handling has been found; however, these workers, working within 100 meters of composting operations, were found to experience only minor effects (Jakubowski 1985). Furthermore, the observed effects may have been the result of irritants produced in the composting process (dust, *Aspergillus*) and related to wood chips rather than the sludge portion of the compost (see discussions under "Environmental Setting" above and in Appendix E for more details).

Incidental human contact and farmworker and family contact with biosolids were evaluated in an extensive study reported by Dorn et al. (1985). The 3-year study covered three geographical areas in Ohio and included 47 farms (164 persons in 78 families were evaluated) receiving annual applications of treated sludge (average of 2–10 dry metric tons/hectare/year; average of 3.6 to 17.8 wet tons per acre per year at 25% solids). (Dorn et al. 1985). The illness rates in the families at their farms were compared with 46 control farms (130 persons from 53 families), all of whom initially participated by cooperating with monthly questionnaires concerning their health and their animals' health, annual tuberculin testing, and quarterly blood sampling for serological testing. It should be noted that the number of participating farms dropped as the study went on, and only 27% of the 93 original farms completed participation in the 3-year study.

A summary of the two study groups and their numbers over the years is shown below:

			Number Participating		
Unit	Study Group	Number Started	1 Year	2 Years	3 Years

Unit	Study Group	Number Started	Number Participating		
Farms	Sludge	47	47	36	13
	control	46	46	37	13
Participants	Sludge	165	165	126	53
	control	130	130	109	37

Source: Comment letter 43, page 17 as cited from Dorn et al. 1985.

The study found that the estimated risks of respiratory illness, digestive illness, or general symptoms were not significantly different between the sludge farm and the control farm residents (Dorn et al. 1985). It also found no observed differences between disease occurrence in domestic animals on sludge and on control farms. The frequency of serological conversions (fourfold or greater rise in antibodies) to a series of 23 test viruses and the frequency of associated illnesses were similar between the persons on sludge and on control farms. The absence of observed human or animal health effects resulting from sludge application in this study of Ohio farms should be considered with the knowledge that relatively low sludge application rates were used on these farms; the rates were lower than typical application rates for agricultural uses in California (which may be as high as 30-40 wet tons per acre per year). Necropsy data and analyses of tissues found significant cadmium and lead accumulations in the kidneys of calves grazing sludge-treated pastures. The consequences of this are not known in terms of either animal health or human health, assuming humans consume the kidney tissue on a regular basis in animals that bioaccumulate trace metals in their organs.

The authors reported that “the possibility of PCB and other toxic organics reaching crop land is an issue of concern to farmers” and indicated that “more research is needed.” They further noted that “caution should be exercised in using these data to predict health risks associated with sludges containing higher levels of disease agents and with higher sludge application rates and larger acreages treated per farm than used in this study” (Dorn et al. 1985). No similar subsequent studies have been performed because the risks were deemed to be low and the costs for such studies are very high.

In addition, results of the evaluation of reportable disease data for California on the known pathogens that could be present in biosolids (discussed above under “Environmental Setting”) showed that there was no apparent association between disease incidence in the general public and the size and location of biosolids application operations. Those counties where the largest quantities of Class B biosolids are being beneficially reused either have no reported outbreaks or incidence of infectious disease associated with those pathogens that might be derived from direct contact with biosolids or have very low numbers of such reports or incidences. Discussions with various health and water quality officials revealed no known infectious illness that could be related to biosolids use (Shaw, Moise, and Starr pers. comms.).

Investigations undertaken by researchers from Cornell University's Waste Management Institute and the University of Georgia at Athens reviewed numerous incidents where residents living near biosolids application sites had reported illnesses which they believed were the result of exposure to biosolids. These incidents included two deaths in which Staphylococcus aureas was identified as a cause. While the medical histories of the patients were reviewed, no samples were taken of the fields or biosolids from which the illnesses were alleged to have come. The published results of the studies noted that while the evidence was anecdotal, S. aureas in biosolids should be of concern to regulators as a health risk because of the number of incidents being reported. (Harrison. 2002; Lewis 2002)

However, there is no direct evidence that S. aureas is present in biosolids or that it is the source of the illnesses reported to the Cornell University and University of Georgia researchers. The National Science Foundation Water Quality Center at the University of Arizona undertook to sample unprocessed sewage and Class A and Class B biosolids, including biosolids in aerosol form, for the presence of S. aureas. The results of this study, published in the journal Environmental Science and Technology, found S. aureas in untreated sewage, but no presence of S. aureas in any of the biosolids samples. It concluded that the Class A and Class B treatment processes are effective in neutralizing S. aureas and that this microbe does not pose a risk to public health. (Rusin 2003)

The GO includes provisions requiring signage and setbacks to deter direct human contact with biosolids. There are also strict controls on the movement of biosolids off of the application site. There are no provisions to preclude human contact (such as fencing requirements), however, and some potential for human contact with biosolids will always exist.

Based on a review of the information presented above, no adverse impacts associated with direct human contact with biosolids at land application sites are expected. Thus, the risks of disease resulting from direct contact with biosolids are considered to be less than significant. Furthermore, the GO reinforces existing regulations and permit conditions and is intended to protect public health and the environment. Therefore, implementation of the GO is likely to result in fewer risks associated with direct contact because its monitoring and reporting provisions represent an increased level of regulatory oversight of land application. No mitigation is required.

Existing large land application operations using Class B biosolids are in remote areas away from housing, schools, water reservoirs, dairies, and food crop production areas.

Thus, current exposure of the general public to biosolids is minimal. Signage and setbacks required under provisions of the GO serve to deter direct contact of the general public to biosolids. Therefore, this impact is considered less than significant. Mitigation Measure 5-1 is recommended, however, to further reduce this impact.

Mitigation Measure 5-1: Review Manual of Good Practices. Although no significant public health risk is expected from direct human contact with biosolids, it is recommended that all individuals or agencies receiving land application permits under the GO receive a manual of good practices that addresses measures to protect human health. The California Water Environment Association Manual of Good Practice— Agricultural Land Application of Biosolids is an example of such a manual (California Water Environment Association 1998).

Impact: Potential for Increased Incidence of Disease Resulting from Direct Human Contact with Pathogenic Organisms in Irrigation Runoff from Biosolids Land Application Sites

Surface waters can transport pathogenic microorganisms from various sources and infect humans who might ingest these waters or be exposed to waterborne parasites that enter wounds. Although this is a common mode of disease transmission in areas of the world with poor sanitation, irrigation waters in California have not been implicated in disease outbreaks associated with infectious agents or other contaminants because they are not typically an untreated drinking water source. Furthermore, the proposed project would not result in a significant increase in disease because irrigation runoff from land where biosolids have been applied must be controlled for 30 days following biosolids application. These controls would be effective in avoiding offsite movement of biosolids under all but the most extreme conditions. During such conditions, when low-probability storm events or widespread flooding occurs, the runoff entering waterways is likely to contain pathogens from sources other than biosolids-amended fields, and the incremental contribution from biosolids is expected to be minimal. As under normal conditions, unless there is a high degree of contamination (not expected from biosolids) and there is a mode of entry (cut or accidental ingestion), it is unlikely that an infectious dose can be delivered under such circumstances. Therefore, this impact is considered less than significant.

Mitigation Measures: No mitigation is required.

Impact: Potential for Increased Incidence of Disease Resulting from Ingestion of Pathogenic Organisms in Crops Grown on Land Application Sites or Animals Fed with Crops Grown on Land Application Sites

Because an increased amount of biosolids will be applied to land as populations increase, there will be an increase in pathogens of human origin entering the soil. Such pathogens could be transmitted to humans through crops grown on biosolids-amended soils or in foods produced from animals fed on crops grown in these soils.

The GO includes various Class B biosolids site restrictions on the timing of planting and harvesting crops at application sites: no harvesting of food, feed, and fiber crops within 30 days of application; no planting of food crops with harvested parts that touch the biosolids/soil mixture and are totally above the land surface within 14 months of application; no harvesting of crops with parts below the land surface within 20 months of application unless the biosolids have been exposed to kill pathogens for at least 4 months on the surface of the soil; and no harvesting of crops with parts below the land surface within 38 months after an application where biosolids have not been exposed to kill pathogens for at least 4 months on the soil surface. The GO also includes restrictions that apply to the harvesting of turf grasses and prohibits for 1 year following application of biosolids, the grazing of animals used to produce milk that will be marketed without being pasteurized. These restrictions act as a further buffer against potential contamination after the significant pathogen reductions achieved by biosolids treatment.

No cases of infectious disease related to food or animals being contaminated with pathogenic microorganisms have been noted in the literature reviewed for this analysis, and discussions with health officials indicate that no such cases have been reported (Starr, Shaw, Cook, and Isozaki pers. comms.). The greatest risk is probably from the transmission of helminth ova from biosolids to grazing animals. However, the concentrations of ova found in biosolids are low, and the risks of disease transmission from this source are low. Bacteria and viral diseases will be prevented if growers follow the provisions of the GO. This impact is considered potentially significant because of the survival times of potential pathogens. The following mitigation measure should be implemented to reduce this impact to a less-than-significant level.

Mitigation Measure 5-2: Extend Grazing Restriction Period to Allow for Pathogen Reduction. For grazing sites where application of biosolids is proposed, the GO should be revised to require that grazing of animals be deferred for at least 90 days after application. The proposed GO should also be revised to require that grazing of animals be deferred for at least 60 days after application of biosolids in areas with average daily (daytime) air temperatures exceeding 50ºF. These measures will promote maximum degradation of pathogens (and SOCs) before grazing animals are exposed to the soil. See also Mitigation Measure 4-2.

Impact: Potential for Increased Incidence of Chronic Human Disease Resulting from Ingestion of Biosolids-Derived Metals in Crops Grown on

Land Application Sites or Animals Fed with Crops Grown on Land Application Sites

As populations increase, an increased amount of biosolids will be applied to land, and there will be an increase in loadings of trace metals to biosolids-amended soils. Potentially toxic levels of metals could be transmitted to humans through crops grown on biosolids-amended soils or in foods produced from animals fed on crops grown in these soils without proper control of biosolids application rates.

EPA extensively assessed levels of risk associated with biosolids-derived pollutants of concern (trace metals and PCBs) that might contribute to chronic diseases in the Part 503 risk assessments (U.S. Environmental Protection Agency 1995). The risk assessment used to establish the conservative national numerical limitations for toxic pollutants examined various pathways (see Appendix E) by which contaminants might become present on edible plant parts or bioaccumulated in animals consumed by humans that grazed or were fed crops grown on biosolids-amended soils. These detailed risk assessments relied on many assumptions about types and amounts of food ingested, number of years of exposure, and a host of other factors (U.S. Environmental Protection Agency 1995).

EPA reports conclude that heavy metals and dioxins have been extensively studied and that it has been shown that they do not have the potential to cause significant effects given the rates at which biosolids are applied and used (U.S. Environmental Protection Agency 1992b, 1995). EPA found that overall cancer risk associated with food ingestions would be reduced by implementation of the Part 503 regulations (U.S. Environmental Protection Agency 1995) from 0.9–5 cancer cases annually to 0.09–0.7 annually. This is an extremely small number of cancer cases and represents very low risk.

There are several issues of concern regarding the level of protection provided by the Part 503 regulations with regard to toxic pollutants. The assumptions used in calculating the risk and the level of risk chosen as appropriate for the development of regulatory levels are a continuing source of controversy. One of the greatest concerns is the choice of risk factors (10^{-4} versus 10^{-6}) for the development of allowable contaminant levels in land-applied biosolids under the 503 regulations. (Harrison et al. 1999.) Many argue that there is no safety factor in the established maximum contaminant levels and that there is not an adequate system to monitor long-term cumulative increases in soil contaminants that could contribute to bioaccumulation in plants and animals and that cumulative impacts could therefore occur over time as soil levels of contaminants build up.

Other issues of concern relate to the bioaccumulation of cadmium in plant tissues consumed by humans; ingestion by children of biosolids-amended soils containing trace metals and other toxic pollutants, particularly in the home garden setting where Class A biosolids may be used; and rates of dietary intake for various contaminants such as arsenic, synthetic organic compounds, and radioactivity (Harrison et al. 1999). Another area of controversy is the exclusion of certain individual pollutants (i.e., chromium) from the cumulative loading restrictions.

No epidemiological studies are available that evaluate biosolids practices in California and their relationship or contribution to the overall intake of various trace metals. EPA and the California Department of Health Services are evaluating risks associated with environmental exposures to various toxic pollutants in the state.

The analysis in Chapter 4, "Land Productivity", concluded that significant metal-related impacts on agricultural soils and land productivity could occur under the proposed GO program for some combinations of California soils and crops but would probably be rare. However, such impacts are not likely to lead to impacts on public health resulting from consumption of affected crops grown in these soils. The basis for this conclusion, as discussed in the environmental setting above, is the soil-plant barrier (Chaney 1980) (used as a basis for the Part 503 regulations), which is the manifestation of toxicity in plants accompanied by impairment of crop yield and desirability, reducing the chances of contaminated plants being consumed except in extremely unusual circumstances. The most notable exception is where crops are grown on cadmium-contaminated soil over an extended period and a high percentage of a consumer's diet is derived from these crops, as reported to have occurred in Japan over a 40-year period (National Academy of Sciences 1996). As stated in Chapter 3, arsenic, molybdenum, and cadmium in particular can be mobile in non-acidic soils and, under certain conditions, can accumulate in bioavailable forms and be potentially toxic to plants in low soil concentrations.

Copper, mercury, and selenium are the only trace metals in the 1998 CASA survey data for biosolids in California that, at maximum reported concentrations, exceed the ceiling concentration limits under the discharge prohibitions of the proposed GO regulation. The GO contains limitations in addition to those in the Part 503 regulations that would limit chromium and molybdenum application to land. None of these compounds is likely to pose a significant risk to health in association with biosolids land application subject to regulation under the GO because of the GO's restrictions on cumulative loadings. Some have argued that biosolids are a source of environmental mercury that can affect local waterways or be volatilized (Harrison et al. 1999). The GO contains provisions that would prohibit biosolids from affecting local waterways. Mercury emissions through volatilization remain a controversial issue, but such emissions pose no threat to public health because mercury is present in biosolids only at low levels (U.S. Environmental Protection Agency 1995).

Because the proposed GO contains the same or more stringent requirements than established under the EPA Part 503 regulations, the project should be protective of public health and pose minimal risk associated with the ingestion of various foods or animal products derived from biosolids-amended soils.

As long as source control programs are effective at keeping metals levels in biosolids below the EPA Part 503 limitations and the provisions of the GO regarding application rates (annual and cumulative or ceiling limits) are enforced, the risk of increased disease resulting from the presence of trace metals should be low and there will be no significant impact on public health. This impact is considered less than significant.

Mitigation Measures: No mitigation is required.

Impact: Potential for Increased Risk of Chronic Disease Resulting from Ingestion of Biosolids-Derived Organic Compounds in Food, Soils, Animals, Dairy Products, or Wildlife

A number of SOCs, such as PCBs, pesticides, and detergent-derived organic molecules, are contaminants that may be present in biosolids. As the amount of biosolids applied to land increases, the levels of these compounds may increase in biosolids-amended soils. These contaminants could be transmitted to humans through various pathways. Because many of the compounds in this category have been suggested as being potential carcinogens or endocrine disruptors (see "Environmental Setting" and Appendix E), a potential increase in their levels may be an issue of public health concern.

There are no annual or cumulative loading limits established for SOCs in biosolids because the risks associated with the presence of these compounds in biosolids is considered to be very low. Concentrations of these compounds in biosolids are generally found to be below detection limits or very low; many of the compounds are highly volatile and do not accumulate in soils or plants (see Chapter 4). However, some compounds, particularly chlorinated hydrocarbons—PCBs and plasticizers such as bis (2-ethylhexyl)phthalate and dioxins—are of concern as cumulative contaminants that can undergo bioaccumulation.

The principal routes of exposure to toxic SOCs that may be present in biosolids include uptake by plants and consumption of the plants by humans, direct contact of edible plant parts with biosolids and subsequent consumption, direct contact by children who play in or ingest biosolids, uptake by plants used as animal feed and subsequent human ingestion of meat or animal products, and direct ingestion by grazing animals with subsequent human ingestion of animal products. Direct human ingestion is a remote possibility and is not considered a significant or likely source of disease. One major source of dioxins on the farm is wood treated with the wood preservative pentachlorophenol, used in constructing outdoor structures for livestock. Cattle chew on such wood periodically and this provides a source of dioxin in meat that could ultimately end up in biosolids used as a soils amendment (Chaney pers. comm.). The EPA risk assessment was based on those conditions considered to represent the worst-case conditions of exposure through various pathways (see Appendix E, Part 2).

Of all the SOCs, pesticides are probably the most researched. The levels found in biosolids, however, are minuscule compared with the levels of those used directly on farms and with typical environmental levels. The epidemiologic study of human exposure on 47 farms in Ohio to biosolids showed no significant differences in health that could be related to biosolids land application, including health effects that could be related to the presence of SOCs in biosolids (Dorn et al. 1985 and National Academy of Sciences 1996).

Currently, the Part 503 rules do not set standards or require testing of biosolids for SOCs. However, the proposed GO monitoring program would require testing of biosolids for PCBs, aldrin, dieldrin, and semivolatile organic compounds. EPA is in the process of proposing a dioxin limit for biosolids, however, and if and when such a limit is developed, it would be applicable to biosolids use. Until there is sufficient justification (i.e., a potentially significant health risk associated with biosolids is identified), it is unlikely that regulations will be developed to establish limitations on the SOCs in biosolids.

The potential for increased risk of disease resulting from the ingestion of SOCs present in biosolids used in land application is considered minor. Most SOCs are found in very low concentrations (U.S. Environmental Protection Agency 1995) and at levels that pose no excessive risk to human health through any of the potential exposure pathways. There are no reports of adverse human acute and chronic toxicity effects resulting from ingestion of plants grown in biosolids-amended soils (National Academy of Sciences 1996). Few adverse human health effects have been found in studies where treated biosolids were fed directly to animals (National Academy of Sciences 1996). This impact is considered less than significant.

Mitigation Measures: No mitigation is required.

Health concerns regarding grazing animals are discussed above and in Chapter 4, “Land Productivity”. Mitigation Measures 4-2 and 5-2 would increase the period after biosolids application during which grazing is prohibited from 30 days to 90 days. These measures would also increase the level of human health protection associated with SOCs in biosolids.

Impact: Potential for Increased Incidence of Disease Resulting from Ingestion of Groundwater Contaminated by Biosolids-Derived Pollutants or Pathogens

As the amount of biosolids applied to land increases with population growth, the potential for leaching of biosolids-derived contaminants to groundwater will increase, potentially resulting in effects on public health. The pathogens that may be present in biosolids that have the greatest chance of reaching groundwater are viruses. As discussed in Chapter 3, “Soils, Hydrology, and Water Quality”, the leaching of nitrates to groundwater is an issue of concern as well, but only on a very site-specific basis and in terms of cumulative effects. The analysis for Chapter 3 found that for certain geographical areas and geologic and climatic conditions, or in areas where groundwater aquifers are near sources of nitrates or already impaired by nitrates, the impacts from application of biosolids are considered potentially significant. As discussed in the setting and Appendix E, nitrates in drinking water can cause a disease in infants and young children called methemoglobinemia. Although the disease is rare, it is an issue of concern, particularly in areas where there are already high nitrate levels in groundwater.

As discussed in Chapter 3, programs are underway under the Safe Drinking Water program to address nitrates and other contaminants that may be introduced into drinking water supplies. The RWQCBs are involved in these programs and the GO will provide a further tool to protect drinking water supplies and provide monitoring data to assess environmental quality. Under the proposed application rates required under the GO, there should be no adverse impacts on public health related to nitrates and biosolids land application.

Contamination of groundwater with biosolids-related trace metals also should not be an issue of public health concern because of the restrictive provisions of the GO. If the groundwater is a part of a basin that is tapped for a potable water supply, public health will be protected by compliance of the water purveyor with existing drinking water standards for trace metals content. For other water users tapping the groundwater aquifer, the GO has protective provisions in the form of prohibitions against groundwater exceedances of drinking water standards, setback requirements, requirements for minimum depth to groundwater, specified application rates, and monitoring requirements.

Unless there are very porous soils with fractured rock underlying them, abandoned wells that are not properly sealed, and high rates of irrigation or rainfall to provide a means of transport, it is unlikely that any viruses present in biosolids will reach groundwater. The GO contains sufficient provisions to prevent such occurrences (setbacks, minimum distances to wells, runoff controls, and prohibitions on long-term storage piles where concentrations of pathogens might be higher if leached to groundwater). The direct effect of biosolids application is considered less than significant.

Mitigation Measures: No mitigation is required.

Although the direct effect of land-applied biosolids on groundwater quality, and therefore public health, is considered less than significant, there are circumstances in California under which cumulative increases in groundwater nitrate levels could pose a significant health risk. See Chapter 13, “Cumulative Impacts”, for a full discussion of this issue.

Impact: Potential for Increased Incidence of Acute or Chronic Disease Resulting from Human Exposure to Aerosols and Wind-Blown Particulates from Biosolids Stockpiling, Composting, or Land Application

As population growth occurs and the beneficial use of biosolids increases, stockpiling, composting, and land application of biosolids will increase, leading to potential increases in human exposure to aerosols and wind-blown biosolids. However, increased exposure is not expected to correlate with increases in disease for the reasons described below.

As described above under “Environmental Setting” and in Appendix E, various studies reported in wastewater aerosol symposium proceedings and other research have shown that aerosols from spray irrigation of treated wastewater do not pose a significant threat to public health. Research on aerosols from land-applied biosolids has shown similar results. For biosolids land application, recent research has been conducted at the Sierra Blanca Ranch in far west Texas in the Chihuahuan Desert, where rainfall is limited, summers are hot and dry, wind velocities are high, and relative humidities are low (Pillai et al. 1996). Temperatures range from 70EF in November to 84EF in August and mean wind speeds range from 2 to 5 mph. Anaerobically digested sludge from New York City is transported by rail to the site and applied as a cake at a rate of 3 dry tons per acre. Residents of the town of Sierra Blanca, about 4 miles from the closest sludge application site, expressed serious concerns about health effects that could result from the sludge-application operation.

This study found the highest levels of bacteria in the immediate vicinity of the hopper loading area, where the sludge was agitated during loading. The highest bacterial population densities were found during low-wind conditions, with counts ranging between 56 and 630,000 colony forming units (CFU) per cubic meter at the hopper loading area and 4,200–250,000 CFUs per square meter within 15–30 meters of the application site. The bacteria detected were aerobic heterotrophic bacteria; none were the pathogenic bacteria, such as salmonella, found in the biosolids. The absence of fecal coliforms and fecal streptococcus in the air samples was notable, considering that the levels measured in the sludge piles at the hopper loading area were 23,000 most probable number per gram (MPN/gm) of wet sludge for *Salmonella* spp., 1.1×10^8 MPN/gm for fecal coliforms and 3.5 x 10^6 MPN/gm for fecal streptococci (Pillai et al. 1996). None of the sites was positive for coliphage (representative of viruses).

The authors of the Sierra Blanca report concluded that, unlike spray irrigation sites, sludge application sites may have minimal potential for generating aerosols under low wind conditions; no aerosols were detected in the study at distances greater than about 30 meters (100 feet) from the hopper loading site. This study confirms the results of others that there is a lack of viruses in air found at wastewater application sites (Brenner et al. 1988, Fannin et al. 1985) under conditions of high agitation and high likelihood for aerosol formation. The results suggest that land application of municipal sludges at 3 dry tons per acre poses little risk of airborne transmission of bacterial pathogens (under geographical and weather conditions similar to those of parts of California) and the population center downwind (4 miles away in the Texas case) is not affected by airborne bacterial pathogens from the sludge application sites. Most biosolids that are land applied have a solids content of about 25% and do not form aerosols in the same volume as spray irrigation. Most liquid biosolids are injected. There are no spray irrigation operations of biosolids in California such as those in use in silvicultural operations in Washington.

Studies of dust generation at the Sierra Blanca site have shown that only 0.026 g of particulate matter had accumulated in samplers after 25 days of continuous sampling (Harris 1996). This is an extremely low level of particulate material.

Bacteria and viruses exposed to air have a much greater die-off rate than those in soils or water as a result of dessication and ultraviolet radiation; thus, any pathogens that may be present in air will not survive as long as those that are buried. The absence of bacteria in particulate samples at distances of more than 30 meters from the hopper loading site indicate minimal aerial transport of biosolids-derived aerosols or dust. Good site management practices, as suggested in Mitigation Measure 5-1, would be appropriate to minimize worker exposure to biosolids-related aerosols.

Isolation of the biosolids application sites from the general public is a major factor in minimizing any potential risk from aerosols and particulates. As the land application parcels are expanded under the GO, environmental commitments and operating criteria contained in the GO will protect public health. The GO acknowledges the concern over potential health effects of dust generated from biosolids. The GO specifies that biosolids application operations and biosolids incorporation activities cannot cause the release of visible airborne particulates from the application site. Because of the safeguards in provisions of the GO against exposure of humans to airborne particulates from biosolids and the scientific evidence available concerning the low probability of human effects associated with aerosols from biosolids, this impact is considered less than significant.

It is noteworthy to add that research on this issue is continuing and that the present lack of information or reported disease associated with exposure to aerosols near biosolids land application sites should not be taken as an indication that there are no risks. Everything that humans do has risks, but as stated in the draft EIR, these risks are considered less than significant for the general population. For active workers in the vicinity of biosolid mixing and application sites, it can be anticipated that exposure to higher levels of potential aerosols (mainly fine particles to which pathogenic microorganisms could attach) is likely.

Under high wind conditions or when Class B biosolids or certain compost products are loaded or spread, there may be exposure of applicators or workers to aerosols or dusts that can contain potentially viable pathogenic microorganisms. To date, health risks are not deemed to be significant; therefore, this impact is considered less than significant. However, the following mitigation measure is recommended and is not required to reduce the level of significance for this impact.

Mitigation Measure 5-3. As part of good management practices, it is recommended that workers who are loading or working near sites where Class B biosolids are mixed or loaded or are applied by surface spreading wear respirators or masks to protect against inhalation of aerosols or fine particles derived from the biosolids being handled.

Mitigation Measures: No mitigation is required.

Impact: Potential for Increased Risk of Disease Resulting from Contact with Biosolids Spilled during Transport from Point of Generation to Application Site

As more biosolids are transported from places of generation to application sites, the potential spills will increase. However, unless a spill results in an injury accident with subsequent human exposure to biosolids, it is unlikely that a spill of biosolids would result in any threat of humans contracting disease. The GO includes numerous provisions that ensure the safety of biosolids transport. The proposed GO requires that the biosolids hauler be trained in spill response procedures designed to prevent spilled biosolids from remaining on roads, being washed into storm drains or waterways, or contaminating groundwater. Specifications in the GO mandate that each truck carry a copy of an approved spill response plan. Therefore, this impact is considered less than significant. No mitigation is required.

Impact: Potential for Exposure of Residents and Agricultural Workers to Unsafe Levels of Radionuclides After Long-Term (50- to 100-year) Application of Biosolids

Naturally-occurring and man-made radioactive materials may enter the wastestream that is being treated at individual POTWs. In some cases, where excessive amounts of radioactive materials are present, this can create hazards for personnel at the POTW and, if conditions persist, to those who contact lands to which biosolids produced by that plant are applied. (Interagency Steering Committee on Radiation Standards. 2003a) Any hazards that exist at POTWs would exist whether or not the plant was producing biosolids and whether those biosolids are applied to land, so impacts on plant personnel are not pertinent to this PEIR.

The potential for radioactive materials to contaminate agricultural fields is a concern of this PEIR. The ISCORS has opined that over the long-term, that is over periods of 50 to 100 years, the application of biosolids containing radioactive materials to fields may lead to impacts on the health of residents and agricultural workers. (Interagency Steering Committee on Radiation Standards. 2003a) Conditions vary widely between POTWs and, based on the survey prepared by ISCORS, radioactive material in biosolids is not a widespread problem. (Interagency Steering Committee on Radiation Standards. 2003b) Further, POTWs may take specific actions that will help them to avoid endangering personnel and keep contamination levels to acceptable levels. (Interagency Steering Committee on Radiation Standards. 2003c)

This impact is considered significant. However, implementation of Mitigation Measure 5-3 will reduce it to a less than significant level.

Mitigation Measure 5-4: POTW Operators Maintain Awareness of Potential Radioactive Materials in the Wastestream. As part of its GO, the SWQCB shall require the operators of POTW that produce biosolids that are to be applied to land to follow the recommendations contained in the ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works for screening, identification, and consultation.

Impacts of Other Activities

Silvicultural Use

The GO would regulate the beneficial use of biosolids for silvicultural activities. It is anticipated that in California this use would mainly occur in tree farming rather than in large-scale forestry operations as in Washington, where liquid biosolids application is conducted to promote silviculture. The information presented above regarding survival of pathogens and levels of trace metals and other contaminants in biosolids, the low probability of aerosol formation, and the lack of evidence of health effects associated with direct contact with biosolids or contact with wind-blown particulate matter from application sites applies to silvicultural uses of biosolids as well as agricultural uses.

The literature on biosolids management in the Pacific Northwest has been extensively reviewed by Henry (1997) for information on environmental effects related to silvicultural operations. Also, the health effects associated with silviculture have been addressed in detail by the Municipality of Metropolitan Seattle in Munger (1983). This work concluded, based on the known quantities of pathogens in Seattle area biosolids and information on infectious dose and level of environmental mobility of pathogens and other contaminants in forestland, that biosolids would pose little or no risk to public health.

Conditions in California (less rainfall and warmer, dryer weather with less humidity than in Seattle) are more conducive than conditions in Washington to pathogen die-off. It is therefore likely that the health risks associated with use of biosolids in silviculture in California would be less than those found for the Seattle area for similar pathogen levels. The runoff control and stream buffers required by the GO would also apply to silvicultural sites, whether the particular use is a small tree farms or a large forestry operation. Based on the results of studies cited above and the controls contained in the GO, this impact is considered less than significant.

Mitigation Measures: No mitigation is required.

Horticultural Use

Horticultural operations may use biosolids to grow turfgrass, cut flowers, and container-grown landscape plants and live vegetable seedling plants for home garden transplanting. The impacts associated with such activities are similar to those cited above for direct contact and aerosols. Use of Class A biosolids for larger scale landscaping projects would be subject to the GO if the material were applied at high rates. Commercial sales of bagged product for smaller scale commercial and residential uses in horticulture would not be governed by the GO.

Use of composted biosolids in bulk can pose a health risk associated with exposure to high concentrations of *Aspergillus* fungal spores, which can cause allergies and pulmonary disease, particularly in susceptible or immunocompromised persons (see

"Environmental Setting" and Appendix E for further discussion). However, the same effects can be found in gardeners working with composts that are not derived from biosolids (Zuk et al. 1989).

Because there would be little chance of ingestion of flowers or other ornamental plants, there is no health risk associated with consumption of such plants grown using soil amended with biosolids. In the worst case, someone may grow the seedlings to full size and eat the food grown in the biosolids-amended container plant; this is an issue of public health concern. This would be a one-time event, rather than chronic ingestion such as the long-term (70-year) exposure to foods grown with biosolids studied by EPA in its risk assessment, and would pose little risk to health.

Use of Class A material and the numerical limits placed on exceptional quality biosolids for unrestricted use should result in protection of the general public from adverse health effects. This impact is considered less than significant. No mitigation is required.

Land Reclamation

The GO would regulate the use of biosolids for reclamation activities. The reclamation uses could include rehabilitation of mined sites, one-time heavy applications to closed landfills to create a condition conducive to planting of a vegetative cover, or the restoration of lands for use as parks, ball fields, or even golf courses. Such intensive uses would normally not occur in areas where there is much public access until the sites are fully reclaimed. Pathogen exposures are assumed to be no greater than for agricultural sites (see "Impact: Potential for Increased Incidence of Disease Resulting from Direct Contact with Pathogenic Organisms at Biosolids Land Application Sites" above). There are no issues related to food grown on the sites, or grazing animals, or wells providing potable water. The same GO restrictions that apply to agricultural application sites would apply to reclamation sites except for limitations related to nitrogen. The proposed GO allows for biosolids application in excess of the nitrogen requirements of vegetation as part of an overall plan for site reclamation. Excess loading of nitrogen could create health risks through nitrate contamination of groundwater used for domestic consumption. The GO requires that, before land application begins, a report must be prepared demonstrating that unacceptable degradation would not occur in these situations. This report must be approved by an RWQCB Executive Officer before the project proceeds. With these controls in place, the public health impacts of biosolids use at reclamation sites are considered less than significant. No mitigation is required.